

ENVIRONMENTAL PROTECTION AGENCY RESEARCH AND DEVELOPMENT FISCAL YEAR 1987 BUDGET REQUEST

HEARING

BEFORE THE
SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT
OF THE
COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES
NINETY-NINTH CONGRESS

SECOND SESSION

MARCH 13, 1986

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ENVIRONMENTAL PROTECTION AGENCY RE- SEARCH AND DEVELOPMENT FISCAL YEAR 1987 BUDGET REQUEST

THURSDAY, MARCH 13, 1986

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE
RESEARCH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2318, Rayburn House Office Building, Hon. James H. Scheuer (chairman of the subcommittee) presiding.

Mr. SCHEUER. The Subcommittee on Natural Resources, Agriculture Research and Environment will come to order.

Today we will consider the administration's budget request for the year 1987 for the environmental research programs of the EPA.

I regret to say that the predominant impression created by this request is one of *deja vu*. Under the administration's proposal, EPA research would be cut about 10 percent, over \$30 million, from the levels that Congress appropriated for 1986. At the proposed levels of about \$295 million, this budget request totally wipes out the modest gains realized in last year's research budget. Taking inflation into account—and speaking in real dollar terms—the fiscal year 1987 budget is about \$117 million less than what EPA was spending on research 5 years ago when the Reagan administration took office. This is a 33-percent reduction in real terms in the research budget in the last 5 years.

Now, this cut—which we think is shortsighted and totally destructive—is beginning to have serious consequences. It is fashionable these days in some quarters to engage in EPA bashing and to lament EPA's so-called interminable delays in implementing environmental laws. But a closer look at these delays and the causes for these delays frequently reveals a very common underlying problem, and that is scientific uncertainty resulting from an inadequate data base.

We have an only imperfect understanding of how contaminants move or how they actually change in ground water. We lack rudimentary health effects data on thousands of toxic chemicals and pesticides. We don't know enough about basic ecology; certainly not enough to predict confidently how organisms altered in a laboratory, genetically altered in a laboratory, will behave if released in the real world.

The conclusion is obvious. The science gap is seriously eroding EPA's ability to protect the public health and the public environment.

All of us in Congress are worried about the deficit and we're all looking at ways to trim fat off the deficit. But it is fiscal folly to charge EPA with protecting the environment unless we give EPA the resources to understand the nature of the problem and to find a way to do it, and find a way to do it cost effectively.

The realities of the budget austerity, we accept; we urgently need to consider new ways to gather the environmental data we urgently need to protect the public interest and the public health and environment. We need to explore ways in which we can overcome the absurdly adversarial relationship which all too often accompanies environmental issues. We urgently need to bring the private sector into a cooperative relationship with government to help fund the research on which intelligent regulation depends and to contribute the same genius in providing solutions which created the problems in the first place, as a side effect, as a byproduct of creating chemical substances of all kinds that have made life richer, more convenient, safer, and more productive for Americans.

There have been toxic byproducts, and we urgently hope that we will find some kind of institutional device to bring industry in as a positive actor in finding solutions, in finding solutions promptly and solutions that are cost effective. We do not want to burden industry with solutions to environmental problems that are not productive, that are not cost effective, that are silly. We know that many of our smokestack industries compete in a desperate competition for global trade. We don't want to tie them with one hand behind their backs. We don't want to put them at a competitive disadvantage with global competitors, global adversaries who not only don't have their hands tied behind their backs but have a very helpful push, frequently, from their own governments. We want to unleash the competitive energies and talents and genius of American industry to compete successfully in global trade. So we're not about to engage in putting any silly burdens on them.

But we do feel that we are a long way from having created the institutional environment in which industry can make a positive contribution to solving some of the residual problems which their genius has produced as a byproduct of chemicals and other substances which have made life richer and better for all of us. And we are determined to search for those kinds of institutional formats, to bring industry in as a positive partner rather than continue some of the absurdly confrontational adversarial, enormously expensive, and wasteful processes that are going on now.

I'm sure we'll have an opportunity to discuss this with you all and with the subsequent panel, several distinguished members of the board of the Health Effects Institute.

I'm looking forward to the witnesses this morning.

[The prepared opening statement of Mr. Scheuer follows:]

OPENING STATEMENT
EPA FY 87 RESEARCH BUDGET

BY
HON. JAMES H. SCHEUER

SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT

MARCH 13, 1986

THE SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND
ENVIRONMENT WILL COME TO ORDER.

TODAY, THE SUBCOMMITTEE WILL CONSIDER
THE ADMINISTRATION'S BUDGET
REQUEST FOR FISCAL YEAR 1987 FOR
THE ENVIRONMENTAL RESEARCH
PROGRAMS OF THE ENVIRONMENTAL
PROTECTION AGENCY.

UNFORTUNATELY, THE PREDOMINANT
IMPRESSION CREATED BY THIS REQUEST
IS A DISTINCT SENSE OF DEJA VU.

UNDER THE ADMINISTRATION'S PROPOSAL, EPA
RESEARCH WOULD BE CUT OVER \$30
MILLION -- NEARLY 10 PERCENT --
FROM THE LEVELS APPROPRIATED BY
CONGRESS FOR 1986.

- 3 -

AT THE PROPOSED LEVEL OF \$295.2 MILLION,
THIS BUDGET REQUEST ENTIRELY WIPES
OUT THE MODEST GAIN REALIZED IN
LAST YEAR'S RESEARCH BUDGET.

TAKING INFLATION INTO ACCOUNT, THE FY 87
BUDGET IS \$117 MILLION LESS THAN
WHAT EPA WAS SPENDING ON RESEARCH
FIVE YEARS AGO WHEN THE REAGAN
ADMINISTRATION TOOK OFFICE -- A 33
PERCENT REDUCTION.

THIS SHORT-SIGHTED PENNY-PINCHING IS
BEGINNING TO HAVE SERIOUS
CONSEQUENCES.

- 4 -

IT IS FASHIONABLE THESE DAYS IN CONGRESS
TO LAMENT EPA'S INTERMINABLE
DELAYS IN IMPLEMENTING
ENVIRONMENTAL LAWS.

BUT A CLOSER LOOK AT THESE DELAYS
FREQUENTLY REVEALS THE SAME
UNDERLYING PROBLEM: SCIENTIFIC
UNCERTAINTY.

- O WE HAVE ONLY AN IMPERFECT
UNDERSTANDING OF HOW CONTAMINANTS
MOVE OR CHANGE IN GROUNDWATER.
- O WE LACK RUDIMENTARY HEALTH EFFECTS
DATA ON THOUSANDS OF TOXIC
CHEMICALS AND PESTICIDES.

O WE DON'T KNOW ENOUGH ABOUT BASIC
ECOLOGY TO PREDICT CONFIDENTLY HOW
ORGANISMS ALTERED IN A LABORATORY
WILL BEHAVE IF RELEASED IN THE
REAL WORLD.

THE CONCLUSION IS EVIDENT: THE "SCIENCE
GAP" IS SERIOUSLY ERODING EPA'S
ABILITY TO PROTECT THE PUBLIC
HEALTH AND THE ENVIRONMENT.

ALL OF US IN CONGRESS ARE CONCERNED
ABOUT THE DEFICIT AND ARE LOOKING
FOR WAYS TO TRIM THE BUDGET.

BUT IT IS FISCAL FOLLY TO CHARGE EPA
WITH PROTECTING THE ENVIRONMENT
UNLESS WE GIVE IT THE RESOURCES TO
UNDERSTAND HOW TO DO IT.

NEVERTHELESS, GIVEN THE REALITIES OF
BUDGET AUSTERITY, WE URGENTLY NEED
TO CONSIDER NEW WAYS TO GATHER THE
ENVIRONMENTAL DATA WE NEED TO
PROTECT THE PUBLIC HEALTH AND
ENVIRONMENT.

WE NEED TO EXPLORE WAYS IN WHICH WE CAN
OVERCOME THE ADVERSARIAL
RELATIONSHIP WHICH ALL TOO OFTEN
ACCOMPANIES ENVIRONMENTAL ISSUES,
AND BRING THE PRIVATE SECTOR INTO
A COOPERATIVE PARTNERSHIP WITH THE
GOVERNMENT TO HELP FUND THE
RESEARCH ON WHICH INTELLIGENT
REGULATION DEPENDS.

TODAY, WE WILL HAVE AN OPPORTUNITY TO
EXPLORE THIS ISSUE WITH SEVERAL
DISTINGUISHED MEMBERS OF THE BOARD
OF THE HEALTH EFFECTS INSTITUTE.

I AM LOOKING FORWARD TO OUR WITNESSES
THIS MORNING, AND I WOULD NOW LIKE
TO RECOGNIZE THE DISTINGUISHED
RANKING REPUBLICAN MEMBER,
CLAUDINE SCHNEIDER, FOR ANY
OPENING REMARKS SHE MIGHT CARE
TO MAKE.

Mr. SCHEUER. And now, before we call on the witnesses, I'd like to recognize the ranking minority Republican member of our subcommittee, Congresswoman Claudine Schneider.

Miss SCHNEIDER. Thank you, Mr. Chairman.

Once more, regrettably, the Environmental Protection Agency is seeking to diminish the research budget, research program, with one notable exception, and that's the acid rain budget. This reduction of 9.5 percent from current budget authority to me is very discouraging, especially when it is adjusted for inflation. It brings us below the level that the budget was for 1973. I think that that is very significant when one recognizes that since 1973 we have had major pieces of environmental legislation which have passed. When one recognizes that we are continually facing the fact that many of the standards that have been set that have been based on the research, based on the data that the Environmental Protection Agency is supposedly collecting ends up in the courts because either industry or the consumer and the environmental community find that the standards are not appropriate and not based on adequate science.

To me, this is yet another way that we can create more of a red tape quagmire, and I find it regrettable that we are not putting enough emphasis on research in the Environmental Protection Agency.

I think the lack of interest in long-term epidemiology studies is also a regrettable reflection that comes from this budget, and I think that if the Federal Government is not making these investments we're not going to see the investments made elsewhere.

In contrast to this sorry state of affairs in the Environmental Protection Agency's R&D budget, the military budget for R&D in 1986 was nearly \$35 billion. In the fiscal 1987 budget, the administration is seeking to increase R&D for the military to \$41.9 billion. However, EPA's R&D budget is less than 1 percent of the whole military R&D at a meager \$325 million.

So, on the one hand I'm happy to see that EPA is finally in agreement with the Congress on the need for an indoor air program; I mean, I have to give both the bad news and a little bit of the good news. At least you were enlightened enough to recognize the value of an indoor air program and to recognize that it is emerging as probably one of the most serious environmental problems of the 1980's. The fact that we don't have adequate science to indicate what effect the furniture resins, carpet adhesives, cigarette smoke, wood burning and kerosene smoke are all having synergistically on our indoor environment, I think, poses the consumer with some considerable concern. And the fact that EPA is going to continue and aggressively pursue some of the scientific research answers to this—I commend you for that.

But in light of the overall R&D request by EPA, I welcome the testimony today of the Health Effects Institute which I believe is showing the way toward a very exciting and successful experiment, and that is by a combination of the public/private partnership. HEI is funded 50 percent by EPA and 50 percent by the auto industry in looking at some of the health effects of the auto industry, and I think combining from both sectors some of the best scientists in the country.

So I look forward to hearing from EPA. I can't imagine that you can persuade me that EPA's research budget is going to be adequate. Quite frankly, I think it's abysmal. But I just think that 10 years from now you gentlemen are going to be the ones that are going to have to look back on some of the crises that have occurred and think, wow, I could have prevented those if I had asked for more funding in certain areas. And the approach that I take to environmental pollution is one of preventive medicine, because it always costs us much more in dollars and much more in human health if we forego addressing those problems today and put them off for tomorrow. Thank you.

Mr. SCHEUER. Thank you very much.

Congressman McCurdy.

Mr. McCURDY. Thank you, Mr. Chairman.

I would concur with my colleague, the gentlelady, with her statement, I think. She hit the nail on the head pretty well.

I would hope that, since we're getting our early shots in here, gentlemen, that—I just have two areas that I'd like for you to specifically cover in your testimony, if you could, and those are in the area of ground water research.

Can you give us an update on the centers for excellence, the University Centers for Excellence at Rice University in Texas, University of Oklahoma, and Oklahoma State University? And also, the progress or the relative standing of the Ada Laboratories, which is one of your EPA labs which concentrates on ground water research, such things as the Garber-Wellington—those are extremely important to each of us.

I think she left, but I was going to say that I'm the ranking Democrat on research and development in Armed Services, and she's right; the Armed Services budget in research is—the request is a phenomenal growth. It won't occur to the extent that she is concerned about, but there will be considerable growth there.

But one of the areas that we've recently made some progress in the Superfund legislation is requiring Federal facilities now to be under the Administrator and to be charged with cleanup of hazardous waste and pollutants in the—in actually the subsoil, I guess. I chaired a panel in the Armed Services Committee on environmental restoration and the DOD programs, so I think we are finally recognizing that even the Department of Defense has a responsibility to not only stop polluting, but to clean up its waste. So I think there is, again, some good news and bad news; but if you could cover those specific items, I think we can save some time this morning, too.

Thank you, Mr. Chairman.

Mr. SCHEUER. All right, then, we'll recognize Mr. Donald Ehreth, the Acting Assistant Administrator, Office of Research and Development of the EPA.

Mr. Ehreth, your remarks will—your prepared statement will be printed in full at this point in the record. And what we hope you would do would be to summarize your remarks in about 10 minutes, and then I'm sure we'll have some questions for you.

STATEMENT OF DONALD J. EHRETH, ACTING ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. EHRETH. Thank you, Mr. Chairman. With me today are several of our Office of Research and Development office directors who will be helping us clarify some of the issues that you've raised in your opening statements. And with your permission, they will help me and assist me in responding to those questions.

I am pleased, even after hearing your introductory remarks, to sit here and discuss with you the President's budget. We do feel that the Agency's capability is, perhaps, even being enhanced; it's certainly being maintained to address several cross-media issues such as those posed by acid rain or pesticides and ground water, as Mr. McCurdy indicated his interests lie; land disposal waste, leaking underground storage tanks, and especially—the newest acronym in the Agency—the toxic air pollutants issues.

The request, as you identified, however, does reflect the deficit targets set by the President to meet the requirements of the Balanced Budget and Emergency Control Act. Specifically, the 1986 resources displayed in the budget document already include our share of the Governmentwide 4.3-percent program reduction, and the 1987 budget request was developed within the overall resource constraints of the Gramm-Rudman-Hollings Act. Therefore our budget as submitted provides the Office of Research and Development \$295 million and 1,786 work-years, as you have indicated.

We operate on three guiding principles which characterize our mission in the Agency as well as help us prioritize and develop our research plan.

No. 1, we conduct the basic and applied scientific and technological research necessary for the development of EPA's regulatory program.

No. 2, we provide scientific and technical support to our client offices.

And finally, No. 3, we disseminate information and data to the scientific regulatory and user communities.

Now, I'd like to highlight several themes which underlie ORD's 1987 budget request.

First of all, we will continue to promote coordination with and support of ORD's client offices, including the regions. This is a very important part of our program development, that our research outputs are jointly planned with our client office partners to ensure that these outputs respond to the Agency's major and most important scientific, technical, and regulatory concerns.

The second theme of our budget centers on our efforts to respond to the new or expanded Agency program requirements. We will significantly increase the Air Toxics Research Program. We plan to undertake—as Mrs. Schneider indicated—a multipollutant indoor air field study program, using newly refined monitoring and exposure measurement techniques. And we are increasing resources to support the land-banning of wastes and the Underground Storage Tank Programs. A wetlands initiative is also included in our proposal to determine the cumulative effects of pollutants on wetlands loss.

And finally, as you indicated—the issues of uncertainty are important to us, as well—we are increasing resources to ensure that the Agency's risk assessment methodologies are of the highest scientific quality.

A third theme is the Agency's commitment to strengthen the ORD in-house research program. With the increased resources we will be able—and coupled with management initiatives—to begin to upgrade our scientific capabilities in scientific ADP computing, as well as analytical equipment to enhance our quality of science and bring ourselves up to the state-of-the-art levels.

Now, to move through the process rather quickly, let me just summarize a few of the media proposals.

In the area of air, increased emphasis will be placed on research to identify, characterize, and determine health risks from potentially hazardous air pollutants in ambient air. An additional \$3.2 million will be provided to expand studies on hazardous air pollutants. The studies using the Total Exposure Assessment Methodology will be expanded. Research on indoor air pollution, including radon, will continue at 1986 levels as part of the ongoing Governmentwide activities of the Committee of Indoor Air Quality.

In the area of hazardous wastes, that program will remain relatively constant at \$50 million for fiscal year 1987, but critical elements of that program will still see increases. Specifically, risk assessment and transport and fate research supporting the land-banning program will be increased by \$1.5 million. Evaluation of alternative technologies for treating and disposing of wastes will be increased by about \$1 million, and research supporting the implementation of the Underground Storage Tank Program will also be increased by about \$1 million.

In the area of pesticides, to respond to the issues of ground water and a newly emerging technology known as biotechnology, we have included increases in our budget to address those very issues. Furthermore, we are accelerating our efforts to develop and validate test methodologies for noncancer end points, and thereby ensure that industry test data are accurate, reproducible, and consistent.

In the interdisciplinary program, we have our research and technical support activities which, by nature, encompass all media. Four significant programs are covered in the interdisciplinary medium. These are exploratory research grants and centers; our risk assessment guidelines; and our technology transfer and technical information transfer program. The primary reduction in the interdisciplinary media is in the exploratory research grants and centers program. This will amount to a reduction in the number of new grants we will award in 1987.

In the Toxic Substances Program, we will see a shift of resources to fund the high priority pesticides research in such areas as biotechnology and health test method development. Efforts will be continued to develop methods which evaluate ecosystem risk as a result of exposure to new and existing chemicals and thereby assessing risks to nonhuman populations and environment; again, to reduce the uncertainties in those assessments that you indicated your concern.

The area of energy contains our acid deposition research, and it does include an increase of \$6.4 million to a total for the EPA

budget of \$55 million for fiscal year 1987. The details are contained in our written testimony, but I'd like to move on and highlight several ongoing research activities that might be of interest to the committee in light of the recent recommendations contained in the Drew Lewis-William Davis Special Envoys' Report on Acid Rain. And, as doing so, I want to stress that this is not an exhaustive list but is intended to provide you with a sense of our current activity in R&D within the broad research areas identified in the report.

The report calls for a comprehensive dry deposition monitoring network. We will have a 30-station network established by 1987, and expect to expand that in future years. The report indicates the need for process level data from different watershed types to determine effects of acid deposition on surface waters. The National Surface Water Survey, as well as our Direct Delayed Response Research Program, will provide much of that data.

The special envoys express a concern that we should better understand the biological changes resulting from acidification of surface waters. Well, we have a field research program in place that will complement our laboratory work on this issue.

Continuing, accelerated research on the potential link between forest decline and acid rain is called for in the special envoys' report. EPA is supporting research on the site characterization of the four forest types.

The report recommends increased attention to the effects of acid rain on materials. ORD has underway a field research program for development of empirical damage functions, and this program sees an increase for 1987.

A major component of the special envoys' report is the recommendation for the development of a control technology commercial demonstration program. For several years, ORD has been involved in the development of the Limestone Injection Multistage Burner—commonly known as the LIMB—technology. We have a multi-partner wall-fired demonstration project underway in Ohio at a 105-megawatt boiler, and right now on the streets we have an RFP for tracking partners to demonstrate a tangentially fired boiler using LIMB technology.

Recognizing that Congress had indicated that \$5 million provided in our appropriations bill was about half of the total share, we are working with the Department of Energy's Clean Coal Technology Program to develop ways of obtaining the Federal share from that program if needed. We will know more as we continue with our RFP process.

I would like to take just a moment to address some of the specific questions raised by Mr. McCurdy, and let me see if I've noted them appropriately here.

One of the issues he was concerned about was in the ground water program in general. Another issue was what the status is on the centers program, specifically, the ground water research consortium center program in Oklahoma. He is interested also in the Garber-Wellington Program in the Ada Laboratory.

In general, as he indicated, most of our ground water research is conducted out of the Ada Laboratory but is also complemented by work in Las Vegas and in the Cincinnati Water Engineering Research Laboratory. The ground water program overall is up by

about \$21 million. The centers program has been increased by about \$400,000 total to bring the total to about \$4.8 million, and that consortium—Oklahoma State, University of Oklahoma, and Rice University—will receive their fair share of that increase. And if I'm not mistaken, that brings them to about \$540,000 a year total support.

With regard to the Ada Laboratory, it is healthy, well, and alive; that is a very important program to us, also, the ground water program, you will see in our budget in an increased emphasis on pesticides in ground water. As a matter of fact, as you look through our budget you will see that most of the emphasis is on determining the transport, the fate, the persistence, or the bioaccumulation and degradation of organic chemicals as they move through the soil system, on into the ground water.

Now, your final question dealt with the Garber-Wellington proposal, and obviously, you are perhaps reflecting upon a letter that we sent to you just recently regarding a proposal from the Garber-Wellington people.

To date, we have spent approximately \$1.6 million with the Garber-Wellington project, and we have produced what was the most important objective of that particular project, which was a management plan in conjunction and cooperation with those people—or support of them, I should say. That plan now exists. There are many cities, counties, and States that are looking for plans such as that to be complemented by information that we might be able to gain on organic constituents as they impact groundwater. So for the most part, our program does focus on organic contamination and model validation for that particular issue.

I think perhaps we're guilty of poor technology transfer in this case, inasmuch as I indicated that is one of our major areas of interest in our program. I think what we might need to do is sit down with the Garber-Wellington people because, for the most part, the information that they're seeking related to contamination from septic tanks exists as a result of some research we conducted about 5 or 10 years ago over a period of about 5 or 10 years, and that information is readily adaptable to their needs as well as to other needs. So perhaps what I might suggest to you, Congressman, is that—what we might do is have a meeting and just discuss those particular issues. But for the most part, the Garber-Wellington aquifer does not lend itself much to organic contamination because, as you have indicated, it is a pretty clean situation there, and you certainly would not want to perturbate it or disturb it by adding some contaminants to it.

That completes my opening remarks, and we are prepared to address any questions that any of you have regarding any part of our budget, Mr. Scheuer.

[The prepared statement of Mr. Ehreth follows:]

STATEMENT OF
DONALD J. EHRETH
ACTING ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE RESEARCH
AND ENVIRONMENT
COMMITTEE ON SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
MARCH 13, 1986

Good Morning, Mr. Chairman,

I am pleased to be here today to discuss the President's 1987 Budget Request for the Environmental Protection Agency's (EPA's) Office of Research and Development (ORD). With me today are our ORD office directors, and as we go through the question and answer period, they will assist me in responding.

The research program at EPA provides the information, developed over both the long and short term, required by the Agency to make technically sound and scientifically credible environmental policy decisions. Our 1987 request provides a stable and sound resource base. This budget enables ORD to maintain the momentum it has gained over the past few years while taking into account the Nation's need to move toward a balanced budget. The Agency's capability to measure, assess, and control the health and environmental risks of such cross-media hazards as those posed by acid rain, pesticides in groundwater, land disposal of wastes, leaking underground storage tanks, and toxic air pollutants will be maintained and/or enhanced.

OVERVIEW

The Agency strongly supports the Administration's efforts to reduce the deficit. This request reflects the deficit targets set by the President to meet the requirements of the Balanced Budget and Emergency Control Act.

Specifically, the 1986 resources displayed in the budget document include our share of the Government-wide 4.3 percent program reduction. The FY 1987 budget request was developed within the overall resource constraints of the Gramm-Rudman-Hollings Act. Our budget request provides the Office of Research and Development with \$295.2 million and 1,786 workyears.

This reflects a conscientious attempt to focus the Agency's research program on areas that will yield the greatest benefit to high priority regulatory programs. Further, this budget allows us to continue our efforts to address the Agency's long-term scientific goals.

HIGHLIGHTS

The Office of Research and Development operates on three guiding principles, which characterize our mission within the Agency: (1) to conduct the basic and applied scientific and technological research necessary for the development of EPA's regulatory program; (2) to provide scientific and technical support to our client offices; and (3) to disseminate our information and data to the scientific, regulatory, and user communities. These principles serve as the foundation for the formulation of this research budget.

Before I address the specifics of our program, I would like to highlight the several themes which underly ORD's FY 1987 budget request. First, we will continue to promote coordination with and support of ORD's client offices, including the Regions. Our media-specific research committee planning process works, and it works well. Assistant Administrators communicate on strategic research issues, the regulatory agenda, and budget targets. The

research outputs are jointly planned with our client office partners to ensure that these outputs respond to the Agency's major scientific, technical, and regulatory concerns. We focus on developing agreement on issues at the Assistant Administrator level and then fashion a responsive research program for each ORD discipline.

A second theme of this budget request centers on our efforts to respond to new or expanded Agency program requirements. To support EPA's Air Toxics Strategy, we will significantly increase our air toxics research program. In indoor air pollution, we plan to undertake a multi-pollutant field study using newly refined monitoring and exposure measurement techniques. Increased resources are provided to support the land-banning of wastes and the Underground Storage Tank programs as a result of the RCRA reauthorization. The biotechnology program is enhanced to assist the Office of Pesticides and Toxic Substances to determine the risks associated with genetically engineered organisms, including pesticides. A wetlands initiative is designed to determine the cumulative impacts of pollutants on wetland loss. Finally, additional resources are provided to ensure that the Agency's risk assessment methodologies are of the highest scientific quality.

A third theme is the Agency's commitment to strengthen the ORD in-house research program. We will intensify our efforts to provide quality science to the Agency with increased support to our in-house research program. This increase, coupled with management initiatives, will allow us to begin to upgrade our scientific capabilities to current state-of-the-art levels.

I would now like to provide you with a media-by-media analysis of this Agency's research budget proposal for FY 1987.

AIR

The air research program will continue to provide the scientific data necessary to develop and implement air quality standards and to ensure compliance with them. We request a program of \$63.3 million in 1987, a reduction of \$5.2 million from 1986. Increased emphasis will be placed on research to identify, characterize, and determine the health risks from potentially hazardous air pollutants in the ambient air. In 1987, an additional \$3.2 million will be provided to expand studies of hazardous air pollutants. The majority of these resources will be used to study total human exposure to toxic pollutants. We will also refine methods for monitoring these pollutants at their source and in the ambient air, and we will model the creation, transport, and fate of toxic components in the atmosphere. As part of this research program, studies using the Total Exposure Assessment Methodology (TEAM) will be expanded. The results will be development of a national profile of exposure to toxic pollutants. The additional resources will be utilized to develop analytical procedures for measuring methanol and formaldehyde in evaporative emissions.

Research on visibility impairment will continue to receive greater emphasis. Establishment of the multi-station monitoring network, which was begun in FY 1986, will continue. When fully operational, there will be up to 30 sites. In addition, studies will be conducted to determine

the relationship between particles (particularly fine-mode organics and sulfates) and visibility.

Research on indoor air pollution, including radon, will continue at 1986 levels as part of the ongoing Government-wide activities of the Committee on Indoor Air Quality (CIAQ). The emphasis will be on conducting field studies to measure exposure to major indoor pollutants, such as VOCs, NO₂, and inhalable particulates. In addition, emissions from indoor combustion sources and construction materials will be characterized and assessed.

Decreases in the program are due, in part, to a reduction of health and monitoring studies of criteria and mobile source pollutants. These studies contributed new data to the lead, ozone, and sulfur dioxide criteria documents being upgraded in FY 1986. In addition, evaluations of control technologies for particles, SO_x and NO_x will be completed.

WATER QUALITY

For the water quality medium, we request a budget of \$24.4 million in 1987, a reduction of \$3.3 million from 1986. The decrease results from completion of: the evaluation of toxic effects of chemicals in sludge; several research studies in the Municipal and Industrial Wastewater engineering programs; a number of research projects related to aquatic life water quality criteria and biological integrity. Our request includes a decrease in the Monitoring Systems and Quality Assurance area, reflecting our decision to externalize, i.e. to recover the costs of a variety of

Quality Assurance materials and services which had been provided free of charge to States, municipalities, and privately-owned testing laboratories. There is a reduction of \$1.5 million in Great Lakes research reflecting completion of several studies on the effects of toxic pollutants along chemical gradients.

Through our scientific assessment activities we will expedite the promulgation of sludge regulations under Section 405 of the Clean Water Water Act. We will provide support to the program office, Regions and States for update, modification, and implementation of human health criteria on a site specific basis for ambient water quality, as well as provide assistance for evaluation of local health hazards from exposure to chemical pollutants and pollutant mixtures. Research will also provide the Office of Water Regulations and Standards with revised ambient water quality criteria and health assessments for 301(g) variance requests.

We will initiate an effort on wetlands research to establish a scientifically-valid framework for categorizing wetlands and measuring the impact of change so that regulatory actions can be effectively tailored to specific problems.

DRINKING WATER

We request a \$22.5 million program for drinking water in 1987, a reduction of \$1.7 million from the 1986 level. There are several areas of emphasis in this research program. We will develop methods for evaluating health hazards associated with mixtures of chemicals in drinking water supplies and additional Health Advisories for specified

chemicals found in drinking water. Methods for assessing and predicting potential health and environmental effects from complex mixtures will be developed or upgraded. This will contribute greatly to EPA's risk management decisions by enabling us to consider the effects of exposure to complex mixtures (as opposed to individual chemicals). In the environmental processes area, we will determine the cost-effectiveness of in-situ aquifer restoration techniques, which will lead to cleanups where previously the cost was prohibitive.

HAZARDOUS WASTE

We expect hazardous waste research to remain relatively constant at \$50.6 million for FY 1987. Critical elements of the program will receive increases. Specifically, risk assessment and transport and fate research supporting the land-banning program will be increased by \$1.5 million, evaluation of alternative technologies for treating and disposing of wastes will be increased by \$0.9 million, and research supporting the implementation of the underground storage tank program will be increased by \$1.0 million. New efforts in other hazardous waste areas will include: initiation of a response to a Science Advisory Board recommendation to conduct a health research program designed to assess the toxicity of dioxin; standardization of subsurface monitoring methods for more reliable ground-water monitoring; and a more cost-effective approach to waste analysis through development of generic analytical methods for publication by the Office of Solid Waste.

We will support the RCRA program with scientific assessments of specific wastes proposed for RCRA listing, as well as revised risk assessment methodologies to accommodate new scientific information. Health research will take on the challenge of validating a major advancement in our ability to assess the risks of complex wastes. The monitoring program will validate existing analytical methods, as well as develop new analytical methods and new methods for subsurface monitoring. Engineering research will continue evaluating and developing both conventional and alternative treatment and disposal technologies in order to improve the protection provided by permitted facilities and to allow the Agency to consider utilizing land disposal alternatives. Environmental processes research will continue validating models for predicting subsurface waste transport and fate in the subsurface in support of both the ground water program and decisions to ban waste from land disposal.

PESTICIDES

In the pesticides area, we propose a \$13.2 million program in FY 1987, an increase of \$1.4 million from the 1986 level. This increase reflects an acceleration of efforts to develop and validate test methodologies for non-cancer endpoints and thereby ensure that industry test data are accurate, reproducible, and consistent. Research will also be initiated to determine the health and environmental hazards associated with genetically engineered pesticides. These efforts will provide reliable testing regimes to assure safety to humans and the environment from microbial pest control agents. In the environmental processes area, research will be initiated to determine the effects of pesticide contamination on groundwater by examining

pesticide uses and characteristics, agriculture practices, and field conditions. This information will provide the Agency with a much sounder base for mitigation of ground water contamination. Finally, efforts will be accelerated to develop environmental risk assessment methods. These activities will be coordinated with toxic substances research in this area and will enable the Agency to determine risks to actual ecosystems from exposure to chemicals.

RADIATION

For radiation, we request a program of \$196.3 thousand, a decrease of \$7.4 thousand from 1986. There are no major changes planned for this program in 1987. We will continue to provide comprehensive radiological monitoring services to the Department of Energy in order to meet that agency's requirements for its nuclear testing programs, particularly at the Nevada Test Site. We will also provide quality assurance support to Regional, State, and contract laboratories involved in environmental sampling of radionuclides.

INTERDISCIPLINARY

The interdisciplinary program contains all of the research and technical support activities which, by nature, encompass all media. For these programs, we request \$19.4 million, which is a decrease of \$5.2 million from 1986.

Four significant programs are covered in the interdisciplinary medium. These are: exploratory research grants and centers; uniform risk assessment guidelines; technical information and technology transfer; and quality assurance management. The primary reduction in the interdisciplinary medium is in the exploratory research grants and centers

programs, which will reduce the number of new grants we will award in 1987. We believe, however, that we will be able to continue to conduct valuable and essential basic research through the over \$13.1 million still planned for our grants and centers program. We also plan to continue our distinguished visiting scientists program, which will bring several eminent scientists to ORD laboratories to conduct state-of-the-art research.

We will continue to develop risk assessment guidelines that will be used to ensure that risk assessments conducted by all offices in EPA adhere to consistent criteria. Also, we will continue to provide policy guidance and audit support to the Agency in implementing quality assurance procedures. These procedures will ensure that the data generated by and for the Agency are of acceptable reliability, accuracy, and validity.

TOXIC SUBSTANCES

In the toxic substances area, we request \$32.4 million in FY 1987, a decrease of \$2.5 million from the 1986 level. This decrease results from the completion of a number of test methods to characterize the effects of chemicals on human health and the environment. Also reflected is a shift of resources to fund high priority pesticides research in such areas as biotechnology and health test method development. Efforts will be continued to develop methods which evaluate ecosystem risk as a result of exposure to new and existing chemicals and thereby assess risks to non-human populations and the environment. Research will be accelerated to develop test methods and control technologies to assure human health and

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environmental safety from products of biotechnology. Health research efforts on extrapolation will further decrease the uncertainty in our ability to quantify exposures and extrapolate from animals to humans.

ENERGY

The multi-media energy medium contains the acid deposition research program. EPA's portion of the acid deposition program will be increased by \$6.4 million to a total of \$55.1 million for FY 1987. The total Federal request for acid rain research under the National Acid Precipitation Assessment Program (NAPAP) is \$85.4 million for FY 1987, approximately the same as in 1986.

Increased resources will be used to initiate an evaluation of the Regional Acid Deposition Model (RADM) through the use of field study data. RADM is an analytical tool which consists of several modules that will be used to: calibrate Lagrangian models; develop control strategies; perform source-receptor analyses; and assess materials damage. A field evaluation will increase the confidence with which we can predict the effects of control options of SO_2 in the environment.

Major emphasis in the base aquatics effects program will be placed on completing the National Surface Water Survey (NSWS) which has been sampling the chemistry and biology of lakes and streams in the United States; and establishing a long-term monitoring program for a regionally-representative subset of lakes and streams identified from the NSWS. Also, we will continue the "Direct/Delayed Response" project to predict temporal responses of surface waters to acidification.

The terrestrial effects program will analyze the first full year of data from the four EPA forest exposure monitoring sites (Whiteface Mountain,

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New York; Shenandoah Mountains, Virginia; Mt. Moosilauke, New Hampshire; and Mt. Mitchell, North Carolina). Preliminary data on spruce/fir, Southern commercial forests, mixed hardwoods, and Western conifers will be examined. Data of this kind, collected and analyzed over several years, will lead to a quantitative evaluation of reported forest damage.

In deposition monitoring, we will continue to operate the 150 station wet deposition National Trends Network, and establish an additional 15 sites for the Dry Deposition Network (for a total of 30 stations).

The materials effects program will expand the laboratory and field testing program to include brick, mortar, and painted surfaces, and will upgrade the surface science studies of materials damage.

That summarizes the major areas of research within EPA's portion of the acid deposition program. Now allow me to highlight several ongoing research activities that may be of interest to the Committee in light of the recent recommendations contained in the Drew Lewis/William Davis "Special Envoys' Report on Acid Rain." I want to stress that this is not an exhaustive list, but is intended to provide you with a sense of ORD's current activity within the broad research areas identified in this Report.

The Report calls for a comprehensive dry deposition monitoring network. As mentioned earlier, we will have a 30 station network established by 1987 and expect to expand that in future years.

The Report indicates the need for process-level data from different watershed types to determine effects of acid deposition on surface waters. The National Surface Water Survey and our "Direct/Delayed Response" research will provide much of that data.

The Special Envoys express the concern that we should better understand the biological changes resulting from acidification of surface waters. We have a field research program in place that will complement our laboratory work on this issue.

Accelerated research on the potential link between forest decline and acid rain is called for in the Report. EPA is supporting research on the site characterization of the four forest types mentioned earlier. Also, surveys of the extent and magnitude of observed forest decline are planned by the U.S. Forest Service.

The Report recommends increased attention to the effects of acid rain on materials. ORD has underway a field research program for development of empirical damage functions.

The effects of acid rain on heavy metals is another concern expressed in the Report. We are conducting a study of cistern water supplies to examine the mobilization of metals.

A major component of the Special Envoys' Report is the recommendation for the development of a control technology commercial demonstration program. ORD has been involved for several years in the development of the Limestone Injection Multistage Burner (LIMB) control technology. The multi-media energy program for LIMB control technology is decreased by \$4.2 million in FY 1987 from a 1986 total of \$8.7 million. This reflects the completion of funding for the full-scale commercial demonstration of this technology in a wall-fired boiler, and the use of a \$5 million Congressional add-on from FY 1986 to partially fund a commercial demonstration of a tangentially-fired boiler. While the Congress acknowledged that the

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\$5 million was only half of the total Federal share, they directed that we look to other sources (e.g., the Department of Energy's Clean Coal Technology Reserve) for the remaining Federal share. We have recently issued a request for proposals (RFP) for the tangentially-fired demonstration which included a reference to the possibility of joint funding through DOE. Various funding options are now being examined.

CONCLUSION

These are some of the highlights from the 1987 research and development budget request. I am pleased with the outcome of this first stage of the budget process. I believe that this budget request reflects the Agency's commitment to our mission, even in these times of Government-wide budget reductions. I also believe that our budget request will provide ORD with the resources we require to continue supporting EPA's vital mission.

This concludes my prepared statement, Mr. Chairman. My colleagues and I will be pleased to respond to your questions on our research program.

Mr. SCHEUER. Well, thank you very much, Mr. Ehreth.

To start the questioning, Congressman David McCurdy of Oklahoma.

Mr. McCURDY. Thank you, Mr. Chairman. And again, I appreciate the direct comments on the three items that I had mentioned. Because I walked in just as you were starting that, can you tell me the funding levels again on the three?

Mr. EHRETH. Yes. The overall ground water program is \$21 million. Now, that includes our exploratory research program, which is our center; that includes our engineering program; that includes our transport/fate program, which is the Ada Program, as well as our monitoring program in Las Vegas.

Mr. McCURDY. And how does that—

Mr. EHRETH. And it does not include the Superfund activities because they have not been reauthorized yet—I'm sorry, sir?

Mr. McCURDY. How does that compare to last year?

Mr. EHRETH. It's about the same. It's up by about \$50,000.

Mr. McCURDY. OK. And the Centers for Excellence?

Mr. EHRETH. Is up a little bit, \$400,000 overall, which should amount to roughly about \$30,000 or \$40,000 increase per center. I think it brings it to \$540,000.

Mr. McCURDY. Very good. And I'll take you up on your invitation to meet on the Garber-Wellington. We'll contact you and try to get some people up to talk about it.

I think technology transfer is the issue, quite frankly, and I think developing that is extremely important and I think they would be willing to cooperate and work to that end.

Thank you, Mr. Chairman.

Mr. SCHEUER. Congressperson Claudine Schneider.

Miss SCHNEIDER. I'd like to ask you about the Great Lakes research, that program that was undertaken several years ago. I wonder what kind of studies have been completed to date, because I notice that the reductions are something like 62 percent that are being made for 1986. So where are we in terms of assessing the Great Lakes region?

Mr. EHRETH. A very valid question. Let me first of all clarify this reduction issue.

Our budget proposal that we submitted to the Congress included approximately \$1 million for Great Lakes. That was subsequently added to by Congress to the tune of about \$1.5 million. Our budgets were progressing sort of in parallel; your bill was progressing through Congress while our budget for 1987 was progressing as well, so our 1987 program reflects a 1986 base continuation.

In the meantime, over the period of time since we started working in the Great Lakes area, we've probably spent in the neighborhood of \$36 to \$38 million, and we have completed a considerable amount of work on the eutrophication issues. Models exist for developing and understanding of loading, as well as the eutrophication buildup. In the meantime, more recently, we will be completing the studies on the Fox River toxics and ecological impact assessments, several of the Great Lakes models that facilitate predictive capability for determining the effects of toxics in transport and fate. That work, we'll be completing. We will be reporting on acute and chronic toxicity of dioxin, furans, and related compounds in

fish tissue and in water columns. We are reporting on methodology for field assessment of the Great Lakes area of concern, and that document itself is probably very valuable because it will be a document that can be used by any of the neighboring States or surrounding States.

In the meantime, one must also address the Great Lakes program from the perspective that there is a National Great Lakes Program Office which has approximately \$4 million of the research, which is also looking at in-lake monitoring, atmospheric transport of toxicants, and several other issues. Unfortunately, they escape my mind right now but several of the things are associated with determining where the toxicants end up—whether it's in the water column, the sediment, or the fish tissue.

Miss SCHNEIDER. Is that it?

Mr. EHRETH. Yes, madam

Miss SCHNEIDER. The studies—I was trying to jot them down as you listed them. There are about—how many of them? Five?

Mr. EHRETH. Oh, no, those are just some of the more—I would say more substantive reports that will be coming out this year. There have been several studies over the period of years after spending, like I said before, approximately \$36 million.

Miss SCHNEIDER. OK. Once—

Mr. EHRETH. We'd be happy to provide that information for you in more detail.

[Information follows.]

The Great Lakes Research Program conducted at Grosse Ile (Large Lakes Research Station) has been devoted to issues related to the International Joint Commission (IJC) areas of concern and the chronic pollution problems with toxic substances associated with "in-place" pollutants. The long-term goal of the program is to develop cause-effect relationships (models) based on site specific (Great Lakes) data. The hypothesis is that observable effects can be related to the source of contamination whether the source be point or nonpoint.

Specific projects carried out in the last few years, or to be completed in the near future, include:

- Model development and guidance document for toxic substances in rivers and streams. (Completed in 1983 for Office of Water).
- Model development for the fate of pentachlorophenol. (Completed in 1985 for several clients).
- Development and implementation of analytical chemistry methods to quantify 209 PCB congeners and other organo chlorine compounds important to the Great Lakes. (Major work completed in 1984, application to different sites is a continuing process).
- Development of toxicity and chemical data bases and model relating chemical gradients to measured biological effects in a Great Lakes area of concern (Monroe Harbor) (1983-1986).
- Development of a model relating effects of resuspension and direct uptake from contaminated sediment (In-Place Pollutants) as applied to the Trenton Channel (Upper Great Lakes Connecting Channels Study) (UGLCCS) (1985-1988).
- Development of probabilistic exposure models using existing data bases for toxic substances in Monroe Harbor and Saginaw Bay. (1985-1988).
- Development of mass balances of contaminants of concern in the Detroit River and Trenton Channel (1985-1987).
- Acute and chronic toxicity of dioxin, furans and related compounds (1985-1986).
- Ecological impact of toxics on the Fox River area of concern (1984-1986).

In addition technical assistance is provided to the Great Lakes National Program Office (GLNPO) the IJC and states which border the Great Lakes. Examples of this technical assistance include:

- Development and application of a Great Lakes in series model for management of sodium (salt) for GLNPO (1985).
- Support for development and maintenance of Great Lakes point source (computer) files. (GLNPO and IJC-Continuing).

- Documentation of Great Lakes models. (GLNPO-1983-1986).
- Participation on IJC and UGLCCS Committees (Continuing).
- Participation on Niagara River Committees (Continuing).
- Participation on Rouge River Technical Advisory Committee.
- Participation on Milwaukee Harbor Modeling Committee. (1983-1986).
- Technical assistance to East Central Michigan Planning Agency-Data base support. (1986).

It should be noted that a complete listing of reports (about 40 pages) produced by the Great Lakes research program has been prepared. This listing is available upon request.

The information produced by the Great Lakes research program is transferred to the Great Lakes National Program Office, the IJC and states for use in regulatory programs or in management decisions. This information transfer is carried out in several ways. These include: scientific papers; project reports; guidance documents; direct participation of researchers on IJC, state, or regional workgroups or committees; direct access to data bases or model computer programs; and technical assistance.

Miss SCHNEIDER. Well, what I'm more interested in, I guess, is, No. 1, how many of the studies that were undertaken were completed; and, No. 2, once those studies are completed, what's the information transfer? And what is your management plan—is there a management plan? Just as we were talking about technology transfer, it seems to me that once we have these studies, if we're going to be reducing the overall research programs, we want to have use of the studies that have been completed by other—you know, lake regions. So I just want to make sure that there has been some funding and some management scheme developed for that information transfer.

Mr. EHRETH. There are two pathways of information transfer. There are our reports, as well as the management type issues that come from the National Great Lakes Program and the International Joint Commission. There is both a Scientific Advisory Board as well as the International Joint Commission that oversees this whole program, and those two bodies collectively use that information to implement just the very thing that you have identified, that is, the management plan for the Great Lakes Program.

Miss SCHNEIDER. OK. One other question about user fees for water quality control. Are you doing any kind of a pilot project to explore the relationship between the lower levels of monitoring versus the amount that is going to be charged to do those tests?

Mr. EHRETH. I'm not sure I know exactly what you're referring—are you referring to—well, perhaps if you might clarify that because I'm not sure—

Miss SCHNEIDER. OK. The water quality control check samples that are—

Mr. EHRETH. Oh, yes. All right.

Miss SCHNEIDER [continuing]. Going to be done, and the proposal is for user fees to pick up that expense.

Mr. EHRETH. OK. We do not have a pilot program. We are going through, if you will, the policy development or the regulatory process right now in our own work group in-house, and we are evaluating that particular issue as to how we might be able to set up an accounting system to collect those very fees and whether or not they would go back to the National Treasury or come into an EPA account. But basically what we're trying to do there is recover the costs associated with just those very things you identified—the check standards, the audit samples, and things of that nature. We find out that, in some cases—and this is never transferred to you officially, but you hear about it through the grapevine—that some people that we actually transfer these samples to turn around and sell them themselves. So we thought we might as well try to recoup some of those costs ourselves because it does burden down our in-house research program as well as our experimental research program to provide those sites with supplies.

Miss SCHNEIDER. Well, there are two questions that come off of your remarks. One is, if people are going to have to pay for these checks, would you not think that the likelihood of such monitoring or spot checking will decline?

Mr. EHRETH. I would not think so because the regulatory process itself establishes the need for certain laboratory audit in number and frequency. Our working group activity will address those very issues, as well as whether or not a pilot effort or some sort of other effort in the field would be necessary.

Miss SCHNEIDER. And who—do you have a mechanism—I understand you're developing a mechanism to collect the fees, but how about a mechanism for checking out the quality of the work of the monitoring?

Mr. EHRETH. Well, our laboratory itself would still be responsible for conducting all the analytical work and determining the quality. The only thing we would do is, we would still have check standards represented by NBS refereed processes and that sort of process.

Miss SCHNEIDER. There's no plan to just pass that off to the private sector?

Mr. EHRETH. Pardon me, ma'am?

Miss SCHNEIDER. There's no plan to pass that responsibility off to the private sector?

Mr. EHRETH. We do not mean that by—that's not what we mean by externalization. We're simply talking about cost recovery. We would still referee that ourselves.

Miss SCHNEIDER. OK. Good. Thank you.

Thank you, Mr. Chairman.

Mr. SCHEUER. Thank you, Madam Ranking Minority Chairman. Congressman Jan Meyers of Kansas.

Ms. MEYERS. I'd like to ask, in your comments on pesticides, you say that there is an increase that is being requested, and that it reflects an acceleration of efforts to develop and validate test methodologies to make sure that industry test data are accurate, reproducible, and consistent. Can you tell me what kinds of tests these are and where the testing is being done?

Mr. EHRETH. Certainly. The tests range all the way from determining the fate of chemicals in an environment, whether it be the aquatic media, the terrestrial media, as well as the effects on the biota in any one of those media. After we have developed the tests and it goes through a validation process, there is an official agency promulgation process as well; and these tests are added to something called subpart M of the FIFRA statutes—the regulatory products of that statute, I should say.

These are the tests, then, that are prescribed as standard methods whenever an applicant desires registration of his pesticide. It is these tests, then, that the agencies rely upon to gather information so that there is consistency as well as predetermined reliability accuracy associated with the data that comes in. So it ranges, as I said, in short, all the way from fate processes to actual effects, both human and nonhuman effects.

Ms. MEYERS. What kind of controls are there on the amounts of pesticides that are used? Are States doing anything to oversee that?

Mr. EHRETH. I'm afraid that I'm really not qualified to answer that whole question because that is an issue that is generally

within the responsibility of the program office itself, the regulatory office. But I do know that there are handling requirements and labeling requirements for pesticides, and there are some interactions between the States and the Office of Pesticide Programs. We'd be happy to try to get that information for you if you'd like more detailed information.

Ms. MEYERS. OK.

Mr. EHRETH. We'd be most happy to try to do that for you, Ms. Meyers.

[Material supplied to Mrs. Meyers office:]

United States
Environmental Protection
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Pesticides Fact Book



Overview of Pesticide Regulation

Products Regulated

Pesticides include insecticides, herbicides, fungicides, rodenticides, fumigants, disinfectants, plant growth regulators and other substances intended to control pests. Approximately 45,000 pesticide products are currently marketed in the United States. The Environmental Protection Agency (EPA) regulates these products primarily on the basis of their pesticidal active ingredients. There are roughly 1,400 "active ingredients" in the 45,000 products now on the market. By combining these active ingredients (such as salts and esters) EPA has defined about 600 distinct active ingredient groups that must be regulated separately.

Approximately 1.2 billion pounds of pesticides costing \$6.5 billion are sold each year. About 70 percent of all pesticides used in this country are applied in agricultural production, 7 percent in home and garden settings, and the remaining 23 percent in forestry, industry and government programs.

The Regulated Community

About 30 major pesticide producers, another 100 companies that market active ingredients, 3,300 product formulators, and 29,000 distributors are subject to EPA health and safety regulations. Pesticide users, including private citizens, are also subject to EPA regulation. It is a violation of the law for any person to use a pesticide in a manner inconsistent with its label. In order to use certain pesticides that EPA has classified for "restricted use," farmers and commercial applicators must complete an approved training program in the proper handling of toxic chemicals.

Statutory Authority for Pesticide Regulation

EPA's regulation of pesticides is mandated by Congress. Through its Office of Pesticide Programs (OPP), EPA administers two statutes:

- The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), last amended by Congress in 1980, which governs the licensing, or "registration," of pesticide products.
- The Federal Food, Drug and Cosmetic Act (FFDCA) which, among other things, governs pesticide residue levels in food or feed crops.

FIFRA was originally enacted in 1947, when it replaced the Federal Insecticide Act of 1910, but Congress has amended FIFRA several times since then. The most important FIFRA amendment was the Federal Environmental Pesticide Control Act (FEPCA) of 1972, which shifted the emphasis from safeguarding the consumer against fraudulent pesticide products to public health and environmental protection. EPA assumed responsibility for administering FIFRA when the Agency was established in 1970. Before that, pesticides were regulated by the U.S. Department of Agriculture (USDA).

How EPA Regulates New Pesticides

EPA is responsible under FIFRA for registering new pesticides to ensure that, when used according to label directions, they will not present unreasonable risks to human health or environment. The law requires the Agency to take into account economic, social, and environmental costs and benefits in making decisions.

Pesticide registration is a pre-market review and licensing program for all pesticides marketed in the U.S., whether of domestic or foreign origin. EPA annually reviews approximately 15,000 registration submissions of various kinds. Only about 15 brand-new chemicals (new active ingredients) are registered each year. Most registration decisions are for new formulations containing active ingredients which are already registered with EPA, or new uses of existing products.

The Agency bases registration decisions for new pesticides on its evaluation of test data provided by applicants. Required studies include testing to show whether a pesticide has the potential to cause adverse effects in humans, fish, wildlife, and endangered species. Potential human risks include acute reactions such as toxic poisoning and skin and eye irritation, as well as possible long-term effects like cancer, birth defects, or reproductive system disorders. Data on "environmental fate," or how a pesticide behaves in the environment, are also required so that EPA can determine, among other things, whether a pesticide poses a threat to ground or surface water.

EPA may classify a product for restricted use if its toxicity warrants special handling. Restricted

pesticides may be used only by or under the supervision of certified applicators trained to handle toxic chemicals, and this classification must be shown on labels. During registration review, the Agency may also require changes in proposed labeling and use patterns. Moreover, if a pesticide is being considered for use on a food or feed crop, the applicant must petition EPA for a tolerance (see subsequent section on Tolerances) and submit appropriate data so that the Agency can define a safe and realistic tolerance level.

A brand-new active ingredient may need six to nine years to move from the laboratory, through full completion of EPA registration requirements, to retail shelves. This time-frame includes two or three years to obtain registration from EPA. The registration process generally begins with an experimental use permit (EUP) issued by EPA to permit pre-market field testing. Subsequently, manufacturers typically submit an application for federal registration to EPA for review. This application must include appropriate health and safety data, and EPA may require further testing to clarify specific health or environmental questions that may arise during registration review.

The estimated average cost for a pesticide producer to comply with EPA's registration data requirements is between \$2.4 million and \$4.0 million per major new active ingredient. This is about four to seven percent of typical total development costs of \$50 million to \$70 million.

Registration of a new formulation containing an active ingredient already registered with EPA requires far less time and expense. Such new product registrations may be completed within six to nine months.

Pending full development of data required for the registration of products which contain existing active ingredients, FIFRA allows conditional registration if EPA finds that the use of the product will not significantly increase the level of risk posed by similar products already on the market. Conditional registrations are subject to immediate cancellation if the outstanding data are not submitted by the time specified. Under special circumstances prescribed by FIFRA, the Agency may also grant conditional registrations for products containing active ingredients not previously registered with EPA. These special circumstances include a finding by EPA that the conditional use of the new pesticide will be in the public interest, that a reasonable time for conducting the required studies has not elapsed, and that use of the pesticide for the period of conditional registration will not present an unreasonable risk.

EPA also evaluates several types of special registration submissions mandated by FIFRA. Experimental use permits under section 5 allow large-scale experimentation in order to develop data for new products or new uses of existing ones. Through emergency exemptions under section 18, EPA may temporarily authorize state or federal agencies to combat emergencies with pesticide uses not permitted by existing federal registrations. Under section 24(c), "special local need" registrations by the states become effective immediately, but may be disallowed by EPA within 90 days.

Tolerances

Under the FFDCA, EPA sets tolerances, or maximum legal limits, for pesticide residues on food commodities marketed in the U.S. Tolerances apply to imported commodities as well as domestically produced food and animal feed. The purpose of the tolerance program is to ensure that U.S. consumers are not exposed to unsafe food-pesticide residue levels.

Before a pesticide can be registered under FIFRA for use on a food or feed crop, EPA must either establish a tolerance or, if appropriate, grant an exemption from the tolerance requirement. Tolerances for raw agricultural commodities are established under section 408 of the FFDCA. Certain pesticide uses also require separate tolerances under section 409 for processed commodities, if residues are expected to concentrate during food processing.

The Agency establishes a tolerance only if residue chemistry and toxicological data indicate no unreasonable risk to lifelong consumers. Tolerances are set at levels no higher than necessary to permit marketing of treated commodities. The Food and Drug Administration and the U.S. Department of Agriculture are responsible for enforcing tolerances for food and feed commodities in commerce. Any commodities with residues in excess of tolerance levels are subject to seizure.

Residue chemistry and toxicology are far more advanced now than 30 years ago, but until recently the basic scientific assumptions behind our regulations had not been re-examined. In the last few years, EPA has consulted with numerous outside experts in an effort to upgrade its traditional tolerance system. A number of changes have been initiated, including refinement of dietary consumption estimates, a new scheme that allows for more extensive use of group tolerances for related crops, and a data call-in program to bring the data-base up to contemporary standards.

Individual tolerances for existing pesticides are being reassessed as part of the reregistration process. (See subsequent section on *Existing Pesticides*.) EPA is also revoking tolerances for cancelled pesticides. Following tolerance revocation EPA can recommend "action levels," where appropriate, for enforcement by FDA and USDA. EPA typically recommends an action level if, following cancellation, unavoidable low-level residues are expected to occur in food commodities as a result of environmental persistence of the cancelled product.

How EPA Regulates Existing Pesticides

In addition to regulating new pesticides, EPA is charged with protecting human health and environment from any unreasonable adverse effects associated with pesticides already registered and in use. To ensure that previously registered pesticides meet current scientific and regulatory standards, FIFRA requires the "reregistration" of all existing pesticides. This is a massive undertaking. The "old chemicals" problem has drawn criticism because EPA has not been able to review and reregister existing pesticides as quickly as Congress originally envisioned. However, EPA has underway an aggressive reregistration effort through its "Registration Standards" and "Data Call-In" programs. Also, whenever data on a registered pesticide indicate that it may be presenting unreasonable risks, EPA initiates a public "Special Review" to determine whether regulatory action is warranted.

Registration Standards

For reregistration, a pesticide initially registered prior to current regulatory requirements must meet the same "no unreasonable adverse effects" criteria that apply to new pesticides. Through its Registration Standards program, EPA is reexamining, by current scientific standards, the health and environmental safety of the approximately 600 active ingredients contained in some 45,000 currently registered products. On the basis of these reviews, the Agency establishes the various conditions registrants must meet in order to reregister pesticide products containing these active ingredients.

These conditions are spelled out in a document known as a Registration Standard. Such conditions typically include requirements for submission of needed scientific data; compliance with product composition, labeling and packaging requirements; and an obligation to compensate other registrants for use of applicable safety data. Certain changes in application methods and label directions may also be required, and some uses may be restricted to certified applicators as a condition of reregistration.

Depending on how the existing data measure up to current registration requirements, the manufacturer of a major active ingredient may incur costs approaching first-time registration costs (ranging from \$2.4 million to \$4.0 million) to comply with EPA data requirements for registration. If existing data largely satisfy registration requirements, the costs of complying with a Registration Standard will be considerably less.

Once a Registration Standard is developed for a given active ingredient, new pesticide products will also be registered according to the terms and conditions of the Standard. The Standards approach eliminates the need for complete data review for individual products and improves the efficiency and consistency of registration decisions.

EPA is proceeding with Registration Standard reviews on the basis of clusters of similar-use pesticides, such as termiticides, grain fumigants, and fungicides. High-volume and food-use pesticides are being assessed first. At the currently planned rate, Registration Standards will be developed for all active ingredients by the late 1990s. At the end of fiscal year 1985 EPA had issued 117 Registration Standards. The table below shows the Agency's progress in completing Registration Standards during the last six fiscal years.

FY-80	6
FY-81	18
FY-82	18
FY-83	23
FY-84	23
FY-85	27
FY-86 (projected)	25

Data Call-In

One of the key questions in doing a Registration Standard is whether a chemical has an appropriate data-base by today's criteria. In many cases the answer is "no." This is not to impugn pesticide registrants. The fact is that data requirements have been tightened over time and many products were registered in earlier years when fewer requirements were in place. EPA has discovered, not surprisingly, that the early Registration Standards have resulted in many requirements for additional data. In order to obtain important data before the Agency completes or even begins a Registration Standard on a chemical, EPA initiated a Data Call-In program in 1981. Letters are sent to registrants identifying long-term chronic testing needs (cancer, chronic feeding, reproduction, and teratogenicity testing) and requiring the initiation of such studies. At the end of fiscal year 1985, EPA completed "calling in" chronic toxicity data for all pesticides applied to food crops.

In addition to its regular data call-in program, EPA has initiated several "special" data call-ins. One was a groundwater data call-in, completed in fiscal year 1984, concerning 141 existing pesticides known to contaminate or suspected of contaminating aquifers.

Special Review

If a registered pesticide shows evidence of posing a potential safety problem, the Agency can conduct a Special Review of risks and benefits in which all interested parties (environmentalists, manufacturers, users, scientists, and the general public) can participate. A notice initiating a Special Review is not a notice of intent to cancel the registration of a pesticide; a Special Review may or may not lead to cancellation.

Depending on EPA's findings during the Special Review process, the Agency may implement various regulatory options available under FIFRA. Often, rather than initiating cancellation or suspension proceedings to reduce risks associated with pesticide use, EPA exercises less drastic options such as restricting pesticide use to certified applicators, requiring protective clothing, and prohibiting certain application methods or use in certain areas. EPA may also decide simply to continue the pesticide's registrations if risk-reduction measures are found unnecessary.

If the pesticide is found to cause unreasonable adverse effects on human health or the environment, EPA may issue a notice of intent to cancel registration. The registrants and others who would be adversely affected are given 30 days to request a hearing. If there is no such appeal, all pertinent registrations are automatically cancelled. If a hearing is requested, cancellation proceedings may take two years or more, and during that interval marketing may continue.

However, if the EPA Administrator finds that continued registration of the

pesticide for a given use presents an imminent hazard to human health, he may suspend it. Such action requires evidence that the risks of continued use outweigh benefits during the two or more years necessary to complete a cancellation hearing.

There are two kinds of suspensions under FIFRA. Under an ordinary suspension, a registrant has a right to request a hearing before the suspension goes into effect. Unlike the cancellation hearing process, which can consume several years, an ordinary suspension hearing may take about six months. But an emergency suspension order is handed down if EPA determines that the risks of continued use outweigh benefits during the six months it would take to hold an ordinary suspension hearing. An emergency suspension order is immediate and absolute; it is the most drastic step EPA can take under FIFRA.

EPA began conducting Special Reviews, originally known as RPARs (Rebuttable Presumptions Against Registration), in 1975. Most of the approximately 70 chemicals initially identified as needing special review have been reviewed since then, resulting in removal of some from the market or changes in the way they are used, in order to reduce risks to exposed populations. Other suspect chemicals have been identified through the Registration Standards Program described above and placed in the Special Review process. Since the program began in 1975, the time required from start to conclusion of a Special Review has generally been from two to six years. However, EPA has recently issued new Special Review procedures designed to expedite decision-making.

State Enforcement Role

Since the 1972 amendments, FIFRA has included provisions for monitoring the distribution and use of pesticides, and issuing civil as well as criminal penalties for violations. For example, it is unlawful under FIFRA to use a registered pesticide product in a manner inconsistent with its label, to alter the approved label or to distribute in commerce any adulterated or misbranded product. The 1972 amendments also authorized "cooperative enforcement agreements" between EPA and the states, and a certification and training program for applicators that qualifies them to use chemicals classified for restricted use.

In the 1978 amendments the states were given primary enforcement responsibility for pesticide use violations, subject to oversight by EPA. Through cooperative enforcement agreements all states but two, Nebraska and Wyoming, have now assumed primary enforcement responsibility. EPA sets FIFRA enforcement policy and conducts compliance monitoring and enforcement programs in these two states. Pesticide applicator and certification programs are also conducted by the states, except in Colorado (where the state has a program only for commercial applicators) and Nebraska, where EPA performs this role.

Cases of pesticide misuse or accidents should be reported to the state agency with lead responsibility for pesticides, generally the state department of agriculture. A list of these agencies is provided in Appendix E. Such cases may also be reported to an EPA regional office. See Appendix C for a map of the 10 EPA regions and Appendix D for a list of EPA headquarters and regional pesticide contacts.

Product Packaging

Pesticides are toxic chemicals that must be stored and handled with care. For this reason, EPA has set requirements to help prevent incidents of pesticide poisoning in residential as well as agricultural settings. In 1979, EPA published regulations aimed at reducing potentially hazardous exposure to pesticides, such as common insect and weed killers and rat poisons routinely used in and around the home. These regulations require that, if pesticides registered for residential use meet certain criteria, they must be marketed in packages with special closures or other safety features commonly known as child-resistant packaging. These standards have a dual purpose: to prevent children from gaining access to the contents and to increase adult awareness that the contents may be hazardous. These requirements are similar to child-resistant packaging requirements first introduced by the Consumer Product Safety Commission in 1972.

In agriculture, EPA-approved labels restrict the use of certain pesticides to trained, certified applicators. In the past, EPA has classified pesticides for restricted use mainly because of acute toxic risks to applicators. However, the Agency has begun using the restricted use classification more broadly, and pesticides may be restricted for other reasons such as long-term health risks or potential ground-water contamination.

The Agency is convinced that the use of "closed systems" for transferring

pesticides from containers to mixing tanks or application machinery will further reduce the likelihood of accidental poisoning. EPA has published voluntary standards, initially proposed by the pesticide industry, to encourage the development and widespread use of closed systems. The Agency is encouraging advanced technology in closed systems, as well as more widespread use of the limited technology now available. EPA is monitoring the results to determine whether a mandatory approach is necessary.

Farmworker Safety

EPA is making a concerted effort to safeguard farmworkers' health through its regulatory, educational, and research programs. Regulations in effect since 1974 have provided basic protection for those engaged in field and hand-labor tasks. They prohibit direct spraying of workers and require protective clothing, post-application field re-entry intervals, and toxic-effect warnings.

EPA is upgrading and expanding the 1974 regulations through a "negotiated rulemaking" process in cooperation with a committee of 25 federal, state, farmworker, grower, and industry representatives. This committee is addressing a spectrum of farmworker issues ranging from specialized protective equipment for pesticide mixers, loaders, and applicators, to enforcement of regulations via federal labeling and state programs. EPA expects the proposed regulations to be ready for publication in the late spring or early summer of 1986.

EPA has prepared two versions of a slide and tape program, one in English and one in Spanish, for presentation to farmworkers and laborers who work with pesticides. Many states are now using these teaching aids. EPA works with other federal agencies, through programs such as migrant clinics, to provide information on pesticide hazards and safe-use practices.

EPA is also studying field exposures, health effects, and the benefits of protective clothing to agricultural workers.

Ground Water Contamination

Depending on their properties and patterns of use, pesticides may leach through the soil and contaminate ground water, especially where the water table is close to the surface and soils are highly permeable. EPA is developing a comprehensive approach to pesticides in ground water focused on existing problems and prevention of future contamination as well—all in the context of a general Ground-Water Protection Strategy.

For pesticides not yet on the market, EPA is using sophisticated environmental chemistry and mathematical models to predict whether a new pesticide has the potential to reach ground water. All prospective registrants of pesticides intended for use outdoors must submit a range of test data so EPA staff scientists can assess the fate of a new pesticide when used as proposed.

For example, the most important properties determining whether a pesticide represents a threat to ground water are its persistence and mobility. In addition, EPA considers the site itself, since local water and soil conditions are important variables in ground water contamination. The Agency has recently published final guidelines providing registrants with detailed technical guidance for developing environmental-fate data.

Existing ground water problems are generally caused by pesticides that entered the marketplace before the current scientific and regulatory standards were put in place. To detect and correct these conditions, EPA is engaged in monitoring ground water in cooperation with the U.S. Geological Survey and various state agencies. EPA is also

planning a nationwide survey of public and private water supplies. The results of these studies will be published in annual reports and scientific journals.

EPA is also taking action to bring all previously registered pesticides up to current ground-water safety standards. On a priority basis, registrants of existing pesticides are required to submit studies to meet the same rigorous requirements that apply to new pesticides. The Agency has recently required updated information on 141 existing pesticides identified as having some potential to contaminate ground water. In some instances, EPA may also require the registrant to conduct monitoring as a condition of continued registration.

Where ground-water contamination is identified, EPA may take regulatory action ranging from selective restrictions to outright bans against the manufacture and use of a pesticide. Where regional restrictions are needed, EPA is working together with state agencies to develop appropriate product labeling. The Agency has also begun to issue Health Advisories to state and local health officials regarding levels of pesticides in drinking water that may pose significant risks.

Data Quality

Beginning in 1976, a series of audits by the FDA and EPA revealed serious deficiencies in tests conducted by Industrial Bio-Test Laboratories (IBT) to support the registrations, in both the United States and Canada, of numerous pesticides and some drugs. The IBT case raised concerns about the integrity of data submissions to EPA. Since then, EPA has taken steps not only to address the IBT case specifically, but generally to assure the quality of data submitted to support pesticide registrations.

The Agency has issued data requirements and new guidelines for conducting studies required for pesticide registration, and has promulgated Good Laboratory Practices (GLP) regulations under both FIFRA and the Toxic Substances Control Act (TSCA). A reorganized laboratory inspection and data-audit program supports EPA's concern for data quality.

In December 1983, the Office of Pesticides and Toxic Substances (OPTS) established a single management unit in the Office of Compliance Monitoring for the data audit and laboratory inspection programs under FIFRA and TSCA. Through these programs, audits are conducted to verify that final reports accurately reflect existing records, and laboratory inspections are conducted to check that laboratories conducting studies on pesticides and toxic substances routinely follow proper scientific procedures. A computerized system tracks study quality from beginning to end. EPA's inspection and audit programs are coordinated with FDA and the National Toxicology Program through interagency agreements.

In 1986, the OPTS plans to develop both Data Audit and GLP Inspection manuals for use by EPA inspectors and scientific staff. The Agency is also developing a comprehensive set of Standard Evaluation Procedures governing how studies submitted by registrants are evaluated by EPA staff scientists. These procedures, covering studies in ecological effects, exposure assessment, residue chemistry, and toxicology, will ensure consistent treatment of major scientific topics in EPA's science reviews and permit greater public understanding of our internal review process.

The IBT problem has been largely resolved; invalid studies either have been or are being replaced. At the end of 1985, the status of 724 IBT studies on long-term health effects such as cancer or reproductive disorders was as follows:

- 461 do not require replacement for one of several reasons: the study is valid, non-IBT data are available, the pesticide is cancelled or not registered, or the type of study is not required for registration.
- 107 studies have been replaced; the new studies have been reviewed by EPA scientists and found acceptable.
- 72 studies have been replaced and are under review by EPA scientists.
- By the end of fiscal year 1986, the remaining 84 studies will have been replaced, according to an established schedule.

Microbial Pesticides

Naturally occurring microorganisms were first registered as pesticides in the late 1940s. Today there are 14 naturally occurring microbial agents, such as bacteria, fungi, viruses and protozoa, registered in about 100 products used in agriculture, forestry, mosquito control, and home and garden applications. These products are known to be pest-specific and of low toxicity to man.

Biotechnology has advanced to the point where genetically altered microorganisms have been developed for use as pesticides. In October 1984, EPA published an Interim Policy on Small-Scale Field Testing of Certain Microbial Pesticides, requiring developers of biotechnological products intended as pesticides to notify the Agency before initiating small-scale field tests. They must also submit adequate information for EPA to assess whether an Experimental Use Permit (EUP) will be required before testing. If an EUP is required, additional scientific data must be submitted to support the safety of the proposed study, and testing may be carried out only under conditions approved by the Agency.

EPA imposes these requirements to help ensure that the experimental release of genetically altered or other exogenous microbes will not result in unforeseen risks to the environment. The Office of Science and Technology Policy, an arm of the Executive Office of the President, has published a comprehensive proposed framework for all federal agencies regulating biotechnological products, including EPA. Its purpose is to ensure safety without stifling innovation in a discipline with enormous potential benefits.

History of Federal Pesticide Legislation

- 1910 - Federal Insecticide Act protects consumers against fraudulent goods.
- 1947 - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires federal registration of pesticides prior to marketing in interstate commerce.
- 1954 - Miller amendment to Federal Food, Drug, and Cosmetic Act requires establishment of 'tolerances' for residues of pesticides on food, feed, and fiber crops.
- 1959 - Amendments broaden scope of products covered by FIFRA.
- 1964 - Amendments tighten provisions regulating marketing of pesticides.
- 1972 - Federal Environmental Pesticide Control Act (FEPCA) shifts emphasis from consumer to public health and environmental protection.
- 1975 - Amendments require review by USDA of major pesticide decisions and regulations, and establish a Scientific Advisory Panel (SAP) for review of major pesticide decisions and regulations.
- 1978 - Amendments authorize a generic system of pesticide registration, based on active ingredients common to numerous pesticide products, and introduce "conditional" registration. Other 1978 provisions include more flexible procedures for "restricted use" classification outside the registration process, delegation of primary use enforcement to the states, and public access to basic health and safety data underlying pesticide registrations so long as "trade secret" information is protected.
- 1980 - Wampler amendment requires peer review of major scientific studies funded by EPA and used in making regulatory decisions.

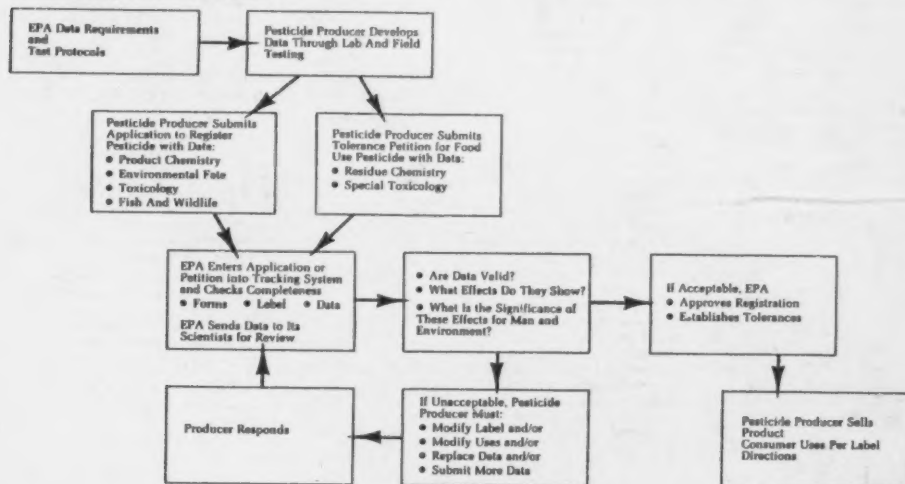
Summary Of Tolerance Provisions: Federal Food, Drug And Cosmetic Act (FFDCA)

- Section 406 Authorizes "action levels" (maximum safe residue levels) for inadvertent residues of pesticides in food or feed commodities.
- Section 408 Requires tolerances (maximum legal residue levels) for residues in raw agricultural commodities. EPA sets tolerances, to be enforced by FDA and USDA, at maximum safe residue levels expected when approved pesticide label directions are followed.
- Section 409 Requires tolerances for food additives. A "food additive" tolerance is required for a pesticide when processing of raw agricultural commodities concentrates residues in excess of Section 408 tolerances. Under the "Delaney Clause," a section 409 food additive tolerance cannot be established for any substance shown to induce cancer when ingested by animals or human beings.

Summary Of The Federal Insecticide, Fungicide And Rodenticide Act (FIFRA), As Amended

Section 2 -	Definitions	Sections 7, 8, 9 -	Registration of pesticide-producing establishments, maintenance of records and right of inspection.
Section 3 -	Basic Registration Requirements	Section 10 -	Trade secret protection for certain data submitted.
§3(c)(5)	A pesticide can be registered if, when used in accordance with widespread and commonly recognized practice, it will not cause unreasonable adverse effects on the environment.	Section 12 -	Unlawful acts (civil and criminal)
§3(c)(1)(D)	Payment of compensation to original data submitters by subsequent registrants.	§12(a)(2)(g)	"it shall be unlawful to use any registered pesticide in a manner inconsistent with its labeling."
§3(c)(2)	Publication of guidelines specifying data required for registration.	Section 15 -	Compensation for economic losses due to EPA regulations.
§3(c)(2)(B)	Additional data to support existing registrations.	Section 16 -	Judicial review of cancellation decisions.
§3(c)(7)	Registration under special circumstances (i.e., conditional registration).	Section 17 -	Notification of foreign governments of suspension and cancellation actions and the export of pesticides not registered in the U.S.
§3(d)(1)	Classification of pesticides for restricted use (i.e., for application only by trained, certified applicators or those under their direct supervision).	Section 18 -	EPA Administrator may temporarily exempt a Federal or State agency from provisions of FIFRA if warranted by emergency conditions.
Section 4 -	Use of restricted pesticides by certified applicators.	Section 19 -	Procedures for the transportation and disposal of pesticides.
Section 5 -	Premarket testing of pesticides under experimental use permits.	Sections 24, 26, 27 -	State authority in registering pesticides and enforcing regulations.
Section 6 -	Procedures for removal of pesticide uses via A. suspension (immediate halt of use while cancellation hearing is conducted) and B. cancellation (permanent ban).		

Pesticide Registration Process



Appendix A

Glossary

Action Levels: Whenever unavoidable pesticide residues occur in food or feed commodities for reasons other than the direct application of a pesticide, EPA can recommend "action levels" (residue levels warranting regulatory action) for enforcement by FDA and USDA. While tolerances are established for residues occurring as a direct result of proper usage, action levels are set for inadvertent residues resulting from previous legal use or accidental contamination.

Active Ingredient: In any pesticide product, the component which kills, or otherwise controls, target pests. Pesticides are regulated primarily on the basis of active ingredients.

Cancellation: The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 6(b) authorizes cancellation of registration if unreasonable adverse effects in the environment and public health develop when a product is used according to widespread and commonly recognized practice, or if its labeling or other material required to be submitted does not comply with FIFRA provisions.

Conditional Registration: Under special circumstances, FIFRA permits registration (see definition below) that is "conditional" upon the submission of additional data. These special circumstances include a finding by the EPA Administrator that a new product or use of an existing pesticide will not

significantly increase the risk of unreasonable adverse effects. A product containing a new (previously unregistered) active ingredient may be conditionally registered only if the Administrator finds that such conditional registration is in the public interest, that a reasonable time for conducting the additional studies has not elapsed, and the use of the pesticide for the period of conditional registration will not present an unreasonable risk.

Data Call-In: Through its Data Call-In program, EPA's Office of Pesticide Programs (OPP) requires the development of key test data, especially on long-term chronic effects, for existing pesticides in advance of scheduled Registration Standard reviews. Data Call-In is an adjunct of the Registration Standards program intended to expedite reregistration (see definition below).

Inert Ingredient: In addition to active components, pesticides contain inert solvents, carriers, surfactants, etc., that are not active against target pests. However, not all inert ingredients are innocuous.

Registrant: Any manufacturer or formulator who obtains registration for a pesticide active ingredient or product.

Registration: Before any new pesticide can be sold or distributed in intra- or interstate commerce, it must be registered under FIFRA. EPA is responsible under section 3 of FIFRA for registration (premarket licensing) of pesticides on the basis of data demonstrating that when used according to approved label directions, they will not cause unreasonable adverse effects on the environment.

Reregistration: Under section 3(g) of FIFRA, EPA is responsible for the reevaluation and reregistration of existing pesticides originally registered prior to current scientific and regulatory standards. EPA reregisters pesticides through its Registration Standards program.

Restricted Use: When a pesticide is registered, some or all of its uses may be classified under FIFRA section 3(d) for restricted use, if the pesticide warrants special handling because of its toxicity. Restricted use pesticides may be applied only by trained, certified applicators or those under their direct supervision.

Special Review (formerly known as Rebuttable Presumption Against Registration, or RPAR): Existing pesticides suspected of posing unreasonable risks to human health, non-target organisms or the environment are referred for Special Review to EPA's Office of Pesticide Programs. Special Review requires an intensive risk/benefit analysis, with opportunity for public comment. If the risk of any use of a pesticide is found to outweigh social and economic benefits, regulatory action may be initiated. FIFRA mandates a range of regulatory options, from label revisions and use-restriction to cancelled or suspended registration.

Suspension: Under FIFRA section 6(c), the EPA Administrator may suspend (halt) the use of a pesticide if necessary to prevent an imminent hazard. An emergency suspension takes effect immediately, but under an ordinary suspension a registrant can request a hearing before the suspension goes into effect to determine whether registrations of the pesticide should be suspended. An ordinary suspension hearing may take six months.

Tolerances: Under the FFDCA, EPA is responsible for establishing tolerances (maximum permissible residue levels) for pesticides in raw agricultural products and processed foods. Whenever a pesticide is registered for use on a food or feed crop, a tolerance (or exemption from the tolerance requirement) must be established. Tolerances for agricultural commodities are enforced by the FDA. Tolerances for meat and poultry products are enforced by the USDA.

Appendix B

Basic Data Requirements For A New Major Food Or Feed Crop Pesticide

Overview: Data from the following tests must be submitted to EPA by a manufacturer prior to registration

Chemistry: list of ingredients (active, inert, impurities)
description of manufacturing process
discussion of formation of impurities
physico-chemical properties (e.g., melting point, solubility, stability, flammability, PH, etc.)
residue studies (original and confirmatory tests for each commodity or commodity group)
metabolic studies
analytical methods (used in setting tolerances for raw agricultural commodities and to detect residues for tolerance enforcement)
results of analytical procedures

Environmental Fate: hydrolysis
leaching
terrestrial dissipation
photodegradation
metabolism (aerobic and anaerobic soil degradation)
rotational crop study

Toxicology: acute oral
acute dermal
acute respiratory
ocular irritation
chronic toxicity (two-year testing of rats)*
subchronic oral toxicity (six-month testing of dogs)**
reproduction and fertility (two-generation study)
metabolism (testing of rats)
mutagenicity
teratogenicity (two species tested)
oncogenicity (two species tested)
Ecological Effects: toxicity (acute) (freshwater aquatic invertebrates)
fish (acute) (two species tested; LC50 = lethal dose for 50 percent of test animals)
bird (dietary) (two species; LC50)
bird (single dose) (LC50)

Note: Many other studies may also be conditionally required depending upon chemical class, site, physico-chemical properties, biological activity and results of basic test requirements.

*Chronic toxicity studies on rats can fulfill one of two species requirements for oncogenicity.

** New guidelines could replace this test with a one-year canine study.

Appendix D

EPA Pesticide Contacts

**Head-
quar^r:** Policy and Special Projects Staff
Office of Pesticide Programs
401 M Street, S.W.
Washington, D.C. 20460
(703) 557-7102

Region 1 Director, Air Management Division
JFK Federal Building
Room 2311-AAA
Boston, MA 02224
(617) 223-2226

Region 2 Chief, Pesticides and Toxic Substances Branch
Woodbridge Avenue
Building 209
Edison, NJ 08837
(212) 264-2525

Region 3 Chief, TSCA/FIFRA Enforcement Section
841 Chestnut Street
(3HW13)
Philadelphia, PA 19107
(215) 597-8598

Region 4 Chief, Pesticides and Toxic Substances Branch
345 Courtland Street, N.E.
Atlanta, GA 30385
(404) 861-4727

Region 5 Chief, Pesticides and Toxic Substances Branch
536 South Clark Street
Chicago, IL 60605
(312) 353-2291

Region 6 Director, Air and Waste Management Division
1201 Elm Street
Dallas, TX 75270
(214) 767-2600

Region 7 Chief, Case Preparation and Technical Assistance Section
728 Minnesota Avenue
Kansas City, KS 66101
(913) 236-2800

Region 8 EPA
One Denver Place
999 18th Street
Suite 1300
Denver, CO 80202
(303) 293-1603

Region 9 Chief, Pesticides and Toxics Branch
215 Fremont Street
San Francisco, CA 94105
(415) 974-8071

Region 10 Chief, Pesticides and Toxic Substances Branch
Mail Stop 524
1200 6th Street
Seattle, WA 98101
(206) 442-5810

Appendix C

Map Of EPA Regions



Appendix E

State Agencies

Region 1		Region 2		Region 3	
Connecticut	Director Dept. of Environmental Protection Hazardous Materials Management Unit State Office Building 165 Capitol Avenue Hartford, CT 06115 (203) 566-5148	New Jersey	Chief Bureau of Pesticide Control NJ Dept. of Environmental Protection 380 Scotch Road West Trenton, NJ 08265 (609) 292-8393	Delaware	Delaware Dept. of Agriculture POB Drawer D Dover, DE 19901 (302) 736-4615
Maine	Director Pesticides Control Board State Office Building - Station 28 Augusta, ME 04333 (207) 289-2731	New York	Director Bureau of Pesticides Dept. of Environmental Conservation Rm. 404, 50 Wolf Road Albany, NY 12233 (518) 457-7482	District of Columbia	Division of Pesticides and Hazardous Materials Dept. of Environmental Services District of Columbia 5010 Overlook Avenue, S.W. Washington, DC 20032 (202) 767-8422
Massachu- setts	Chief Pesticides Bureau Dept. of Food and Agriculture 100 Cambridge Street, 21st Floor Boston, MA 02202 (617) 727-7712	Puerto Rico	Director Analysis and Registration of Agricultural Materials Puerto Rico Dept. of Agriculture POB 10163 Sanjurjo, PR 00908 (809) 796-1710, 1715	Maryland	Chief, Pesticide Applicator's Law Section Maryland Dept. of Agriculture 50 Harry S. Truman Parkway Annapolis, MD 21401 (301) 841-5710
New Hampshire	Supervisor Pesticides Control Division Dept. of Agriculture 85 Manchester Street Concord, NH 03301 (603) 271-3550	Virgin Islands	Director Pesticide Programs Division of Natural Resources Management Dept. of Conservation and Cultural Affairs 111 Watergut Homes Christiansted, St. Croix U.S. Virgin Islands 00820 (809) 773-0565	Pennsylva- nia	Chief, Agronomic Services Bureau of Plant Industry PA Dept. of Agriculture 2301 N. Cameron Street Harrisburg, PA 17110 (717) 787-4843
Rhode Island	Chief Division of Agriculture and Marketing Dept. of Environmental Management 22 Hayes Street Providence, RI 02903 (401) 277-2782			Virginia	Supervisor VA Dept. of Agriculture and Consumer Service POB 1163 Richmond, VA 23209 (804) 786-3798
Vermont	Director Plant Industry Division Dept. of Agriculture 116 State St., State Office Bldg. Montpelier, VT 05602 (802) 828-2431			West Virginia	Director, Plant Pest Control Division W VA Dept. of Agriculture Capitol Building Charleston, WV 25305 (304) 348-2212

Region 4		Region 5		Region 6	
Alabama	Director Ag Chemistry/Plant Industry Division Alabama Dept. of Agriculture & Commerce POB 3338 Montgomery, AL 36193 (205) 832-3733	Illinois	Chief Bureau of Plant and Apiary Protection Dept. of Agriculture Emmerson Building Springfield, IL 62706 (217) 785-2427	Arkansas	Director Division of Feed, Fertilizer and Pesticides Arkansas State Plant Board 1 Natural Resources Rd. Little Rock, AR 72205 (501) 225-1598
Florida	Administrator Dept. of Agriculture and Consumer Services Mayo Building, Room 213 Tallahassee, FL 32301 (904) 487-2130		Office of Health Protection Dept. of Public Health 535 West Jefferson Springfield, IL 62761 (217) 782-4674	Louisiana	Office of Agricultural and Environmental Sciences Louisiana Dept. of Agriculture POB 11453 Baton Rouge, LA 70804 (504) 925-3763
Georgia	Chief Pesticides Division Dept. of Agriculture 19 M.L. King, Jr. Drive, S.W. Atlanta, GA 30334 (404) 656-4958	Indiana	Pesticide Administrator Office of the State Chemist Dept. of Biochemistry Purdue University West Lafayette, IN 47907 (317) 494-1587	New Mexico	Chief Division of Agricultural and Environmental Services N. M. State Dept. of Agriculture POB 3150 New Mexico State University Las Cruces, NM 88003 (505) 646-2133
Kentucky	Director Division of Pesticides Kentucky Dept. of Agriculture Capitol Plaza Tower Frankfort, KY 40601 (502) 564-7274	Michigan	Plant Industry Division Dept. of Agriculture Lewis Cass Building Lansing, MI 48906 (517) 373-1087	Oklahoma	Supervisor Pest Management Section Plant Industry Division Oklahoma State Dept. of Agriculture 310 N.E. 28th Street Oklahoma City, OK 73105 (405) 521-3863 or 3871
Mississippi	Director Division of Plant Industry Dept. of Agriculture and Commerce POB 5207 Mississippi State, MS 39762 (601) 325-3390	Minnesota	Director Division of Agronomy Services Dept. of Agriculture 90 West Plato Blvd. St. Paul, MN 55107 (612) 297-1161 or 296-1161	Texas	Director Division of Agricultural and Environmental Sciences Texas Dept. of Agriculture POB 12647 Austin, TX 78711 (512) 463-7524
North Carolina	Pesticide Administrator Pest Control Division Dept. of Agriculture State Agriculture Building Raleigh, NC 27611 (919) 733-3556	Ohio	Specialist in Charge of Pesticides Dept. of Agriculture 8995 East Main Street Reynoldsburg, OH 43068 (614) 866-6361		
South Carolina	Pesticide Supervisor Plant Pest Regulatory Service 210 Barre Hall Clemson University Clemson, SC 29631 (803) 656-3005	Wisconsin	Executive Assistant Dept. of Agriculture, Trade and Consumer Protection POB 8911 Madison, WI 53708 (608) 287-9423		
Tennessee	Director Plant Industries Division Dept. of Agriculture POB 40627, Melrose Station Nashville, TN 37204 (615) 360-0117				

Region 7

Iowa Supervisor
Pesticide Control Section
Iowa Department of Agriculture
Henry A. Wallace Building
East 7th Street and Court
Avenue
Des Moines, IA 50319
(515) 281-8590

Kansas Director
Plant Health Division
Kansas State Board of
Agriculture
109 S.W. Ninth Street
Topeka, KS 66612
(913) 296-2263

Missouri Supervisor
Bureau of Pesticide Control
Dept. of Agriculture
POB 630
Jefferson City, MO 65102
(314) 751-2462

Nebraska Director
Bureau of Plant Industry
Nebraska Dept. of Agriculture
301 Centennial Mall
Lincoln, NE 68509
(402) 471-2341

Region 8

Colorado Supervisor
Pesticide Section
Division of Plant Industry
Colorado Dept. of Agriculture
4th Floor, 1525 Sherman Street
Denver, CO 80203
(303) 892-2838

Montana Administrator
Environmental Management
Division
Agriculture-Livestock Building
Rm 317
Capitol Station
6th and Roberts
Helena, MT 59601
(406) 444-2944

North Dakota Director
Plant Industries Division
Dept. of Agriculture
State Capitol
Bismarck, ND 58505
(701) 224-2232

South Dakota Director
Division of Regulatory Services
SD Dept. of Agriculture
Anderson Bldg.
445 East Capitol
Pierre, SD 57501
(605) 773-3375

Utah Director
Division of Plant Industries
Dept. of Agriculture
350 North Redwood Road
Salt Lake City, UT 84103
(801) 533-4107

Wyoming Manager
Plant Industry
Wyoming Dept. of Agriculture
2219 Carey Avenue
Cheyenne, WY 82002
(307) 777-9321

Region 9

Arizona Administrator
Board of Pesticide Control
1624 West Adams - Suite 103
Phoenix, AZ 85007
(602) 271-3578

State Chemist
Agriculture Experiment Station
POB 1586
Mesa, AZ 85201
(602) 833-5442

Executive Secretary
Structural Pest Control Board
2207 South 48th - Suite M
Tempe, AZ 85282
(602) 271-3664

California Assistant Director
Division of Pest Management,
Environmental Protection, and
Worker Safety
California Dept. of Food &
Agriculture
Sacramento, CA 95814
(916) 322-6315

Hawaii Head
Division of Plant Industry
Hawaii Dept. of Agriculture
POB 22159
Honolulu, HI 96822
(808) 548-7124

Nevada Administrator
Division of Plant Industry
Nevada Dept. of Agriculture
POB 11100
Reno, NV 89510
(702) 789-0180

Guam Director
Air and Land Programs Division
Guam Environmental Protection
Agency
POB 2999
Agana, GU 96910

American Samoa Director
Dept. of Agriculture
POB 366
Pago Pago, American Samoa
96799

Trust Territory of the Pacific Islands Executive Officer
Trust Territory Environme. 'a)
Protection Board
Office of the High Commissioner
Trust Territory of the Pacific
Islands
Saipan, Mariana Islands 96950

Commonwealth of the Northern Mariana Islands Environmental Engineer
Division of Environmental
Quality
Commonwealth of the Northern
Mariana Islands (CNMI)
Dr. Torres Hospital
Saipan, Mariana Island 96950

Region 10

Idaho	Supervisor Pesticide Specialist and Registrar Idaho Dept. of Agriculture POB 790 Boise, ID 83702 (208) 334-3240
Oregon	Assistant Chief Plant Division Oregon Dept. of Agriculture 635 Capitol Street, N.E. Salem, OR 97301 (503) 378-3776
Washington	Pesticide Specialist Washington Dept. of Agriculture 406 General Administration Bldg. Olympia, WA 98504 (206) 735-5064
Alaska	Alaska Dept. of Environmental Conservation POB 1088 Palmer, AK 99645 (907) 745-3236

Ms. MEYERS. Thank you.

Mr. SCHEUER. Thank you.

Congressman Bob Smith from the State of Vermont—New Hampshire. [Laughter.]

Mr. SMITH. I would just say that Vermont is a nice State, Mr. Chairman.

There seem to be, as you read the budgetary information and at the same time hear the problems—especially in the areas of ground water contamination, hazardous waste sites, acid rain—we just don't seem to be getting the dollars placed in the areas where we need them. Obviously, I realize we're in a tough budgetary situation, but specifically, let me deal with—for a second—the ground water research. There are cutbacks there, and yet it's obvious as you go up and down the east coast and all across the country, you find evidences of more and more ground water contamination and our whole water supply is so tied into that in most areas.

Where are we going? I mean, is this the place we should be making these kinds of reductions, given the fact we know we have to prioritize? I'd just like your comment on that in terms of whether you feel what we have is enough.

Mr. EHRETH. Well, perhaps part of the problem can be cleared up by saying that obviously there is some confusion in the way we present the budget because the ground water program actually increases by about \$50,000 overall for 1987 over 1986. But what you're probably seeing in there is on a media-by-media basis, some ups and some downs. For instance, a recent issue that is emerging as of critical importance is the issue of pesticides in ground water. And so we have reoriented money to deal specifically with pesticides while, in the meantime, we are focusing most of our attention on organics in general and the flow of organics as they are, perhaps, leaked from a landfill or a Superfund site or whatever as they move down through the soil system and on into the ground water and perhaps then are detected in well water. In the drinking water program, for instance, the whole regulatory process is focusing heavily on volatile organics as well, so our emphasis is, in fact, on volatile organics; the organic constituents in pesticides for the most part are organics.

So this is an area that I think we are concentrating on, and it is an area that has continually increased, sometimes by larger amounts than this year's budget would indicate, but it is an area that has continually been receiving support.

Now, the one thing also that I must clarify is that our budget submission currently does not reflect the Superfund increment of ground water research which has been traditionally about \$3 million to \$4 million more, so that's maybe another aberration of the process.

Mr. SMITH. On the Superfund for a second, obviously that's bogged down in Congress at the moment; hopefully it will get unbogged and get out—the problems that we face in this area are just so unbelievable. How are we ever going to get the resources that we need to clean up these sites with the kind of budgetary constraints that we have now? Basically all we're looking at here for the most part—acid rain and pesticides are an exception, as I see in here—but we're seeing essentially freezes or slight reductions or

slight increases. There's no dramatic increases in any of these areas that would reflect the magnitude of the problem that we're hearing all across this country in terms of ground water contamination, and I'd add a second question to that. It's my sense in talking to EPA that there seems to be some hesitation in the area of permanent cleanup technology; I think for the first 5 years of the Superfund Program we identified a lot of sites, but we didn't clean too many of them up, although I think with the limited amount of resources we had, we tried.

But now we're looking at a roughly \$10 billion Superfund that hopefully—if it ever gets out of Congress—what about permanent cleanup technology? Is there a real, genuine understanding of that in EPA in the sense that it is necessary, that it doesn't make sense to shift from one site to another and create more—and I know I've got a big question there, but—

Mr. EHRETH. No; it's a very good question. I think it's a question that we enjoy answering. I'd like to ask Dr. Skinner to convey to you some of the things that we are doing in technology, especially a new and a very exciting program that he recently developed.

But in response to the first part of your question, which is the Superfund authorization system or process itself, I'd like to try to paraphrase just what the Administrator said yesterday and has said on several days recently, and that is, please, Congress, pass the bill because we are getting to a situation where we will have people that will be losing their jobs, contracts will be shut down, and we're rapidly approaching that date. So that's the first step. And in that bill, there is authorization for doing several of the things that you are concerned about, both in the way of research as well as permanent cleanup.

But perhaps Dr. Skinner can talk to you about the technology program because it is very exciting.

Mr. SKINNER. Yes. I repeat the point that Mr. Ehreth made about the fact that the current Superfund—before the recent set of amendments—really doesn't provide us authority to do research under the Superfund statute. All we can really do is technical support of the program. With the amendments, there would be direct authority to do research; and one of the areas where we would focus that research, among others, would be on innovative and new technologies. And we've actually initiated a small program this year which would evaluate some of the innovative technologies and provide cost information and performance information so that they could be used in Superfund cleanups. And under the amendments, that would be an entire new impetus for evaluating those technologies.

Mr. SMITH. Thank you, Mr. Chairman.

I might just make one comment. On top of all of the environmental problems with the toxic waste and ground water contamination in 13 or 14 Superfund sites, the highest per capita of any State in the Union, we now have two nuclear waste repositories on either side, one in Maine on the border of New Hampshire and the other in southwestern New Hampshire. So sometimes you wonder who your friends are, Mr. Chairman.

Mr. SCHEUER. Right. And you also wonder whether nuclear wastes and nuclear incineration respect State boundaries.

Well, Mr. Ehreth, we've benefitted greatly from your testimony, and I must say that I respect the job that you've been doing since you've had this job. I respect your bona fides. I respect the effort and industry that you have invested in doing your job and your clear intent to do the best job you could and to keep things going.

Now, having said that, the Office of Research and Development has been without an appointed Assistant Administrator for about 8 months, and that inevitably does take its toll. There's a feeling around here that that—with absolutely no reflection on you, and I want to make that clear beyond any conceivable possibility of doubt because we have been critical in the past years of some EPA personnel at a high level, and I want to avoid any suspicion that we engage habitually in EPA trashing; we don't. There are some excellent people in there, and you are one of the ones who has really gone to the well. You have given it your level best, and I respect you and I admire you.

Nevertheless, this position should be filled and it should be filled promptly to avoid the kind of drift and disorder that we've seen in the past, specifically under the reign of—I won't use that expression—under the Burford administration, let us say. We want to avoid that, and I'm sure you want to avoid that, too.

Can you tell us whether any progress is being made in identifying and finding a top-level person with impeccable credentials to fill that role of Assistant Administrator?

Mr. EHRETH. Yes. I can happily say to you that this Administrator has assigned this as one of his top priorities, and he has engaged the services of the Science Advisory Board, as a matter of fact, to advise him on potential candidates for the position. And there are at this very moment several interviews being conducted of potential candidates, and I, like you, eagerly await my new leader.

Mr. SCHEUER. When did he engage the services of the Science Advisory Board?

Mr. EHRETH. It's right from the start. He engaged the Chairman of the Science Advisory Board, Dr. Goldstein himself, and others to advise him on those people. So this has been a very active process and the intensity has been increased significantly in the past 2 to 3 months.

Mr. SCHEUER. That's encouraging.

Let me revert to the subject that Congressman Smith raised. I was up in his State; we had a hearing together there on the ground-water problem. I suppose I could spend full time traveling around the United States having hearings in the 50 States, the 49 other than my State, on their ground water problems. I don't think there's a Member of Congress that doesn't have ground-water problems in his States, and this indicates how all-pervasive this problem is. We haven't learned how to clean up ground water. We haven't learned how to monitor ground water. We haven't learned how to predict when we're going to have a ground water problem from activities that are taking place above the surface. We haven't been able to identify the pesticides that are going to end up in the ground water. We were assured by industry many, many times that such and such a pesticide would never end up in the ground

water, only to find 2 or 3 or 4 or 5 years later that they were in the ground water.

Yet, there doesn't seem to be any visible effort to get the ground-water problem under control in terms of our knowledge base, of what to do, forgetting about the technology. But since ground water comes as a result of what happens above, on top, basic knowledge about ground water travel, the transformation that takes place, the transport of toxic chemicals is one of the most indescribably complicated, esoteric scientific conundrums, I think, that the mind of man has ever been challenged by. The transport of toxic wastes up there and the transport of ground water down there—we can stand on Earth and look—if we could look below us, and then we look above us, and these phenomena are indescribably complicated. But yet, they affect our lives with visible impact. All you have to do is watch the television screen to see the impact that ground water problems have on a neighborhood, the toxic waste problems and the ground-water problems. They absolutely create turmoil, anguish, embittered emotional controversy in communities.

When are we going to do enough research? When is the research on ground water going to be of sufficient level of magnitude to enable us to really come to grips with it, to cope with it, to be able to tell human beings and corporations on Earth how they must restrict and control their activities to diminish this—or eliminate—the ground water problem? And when are we going to be able to achieve the knowledge base that will help us attack the ground water problems that are there now, as I said, in, like, 50 States?

Mr. EHRETH. Well, I'm a little bit more positively disposed to the current state of affairs. I think that we have come a long way with regard to understanding the transformation and fate of chemicals as they move through the soil system and on into ground water. Our understanding of multidimensional flow, as well as the transformation processes occurring as that pollutant travels through that soil media, is better understood today. Our ability to monitor ground water has been enhanced significantly over the past several years. It's been about 10 or 12 years now since we've mounted an intensive effort in ground water pollution control and established Ada as our own research center, our center of expertise.

We have made several advances in that measurement and monitoring capability, as I said. I think also it's demonstrated by the fact that we have two very important technology transfer functions supported by Ada on an annual basis, and that is the Groundwater Information Transfer Center as well as the Modeling Information Center. And in transferring that information on to the users, we have been able to help States and localities develop management plans. It's just that I think we discover new problems on a day to day basis, and the principal concerns are associated with health effects. And health effects take a long time to determine; they are several years in the running. And so, consequently, what we need to do—as we are doing—is continue our Health Effects Program to learn more about what happens when chemicals are taken in by humans or nonhuman targets.

Miss SCHNEIDER. Mr. Chairman, will you yield?

Mr. SCHEUER. Yes.

Miss SCHNEIDER. Thank you for yielding, Mr. Chairman.

I just wanted to see if there was a reflection in the budget on ground water insofar as a priority issue is concerned with EPA and your various R&D programs, to what degree you think the ground water problem is a serious one. I keep hearing reports from the Interior Department, from a number of different Federal agencies, from local government; and it seems that everywhere we turn, there are more and more warning signals about ground water, and it covers essentially two different areas: one, supply of ground water, and then the quality—or lack of quality—of ground water.

I guess one of the things that concerns me is that this may be more of a silent problem than we might expect, much like the hazardous waste situation when we first anticipated that there were a limited number of Superfund sites. Now we're overwhelmed with how contaminated our land is.

Do you have the feeling—and also, do you have the mechanism in place—to be prepared to deal with a much more all-encompassing ground-water problem?

Mr. EHRETH. We took our Ground-Water Research Program to a Science Advisory Board panel just last year, as a matter of fact, and had them take a look at not only our Ground-Water Research Program but the way the Agency manages its overall Ground-Water Program. And in that program, several things came out of that which we recently have implemented which focus better management attention and consolidate a lot of the responsibilities and authorities for making decisions on where our ground-water research is headed.

So I think, after having implemented some of those ideas and some of those concepts, that yes, we are in a better position to respond to those types of priority crunches.

In the meantime, I think ground water does enjoy a high priority in our own program as well as the Agency overall because, in view of—in the presence of Gramm-Rudman, it is one of those areas that is reflected to stay constant, if not slightly increase. And so consequently, I have to say to you that that is a high priority to us.

Mr. SCHEUER. We have two bells up there, and we're going to recess in about one minute. But I'm going to ask you a question now, and then you can give us the answer when we come back.

Mr. Ehreth, we see in the newspaper this time—I don't know if it's in the Washington Post, but it's in the New York Times, a column by Phil Shabecoff—that President Reagan will endorse a report calling for action to curb acid rain. And his endorsement will come, says Shabecoff, when he meets here with Prime Minister Brian Mulroney of Canada next Tuesday. Now, that will be some kind of a commitment. We've seen the text of what they're developing and it doesn't call for a heck of a lot of action. And we hope that before long we'll be putting some meat on that skeleton and calling for some real controls. There will be a control program, but we notice from your budget that you cut the acid rain control technology program by 57 percent from last year. Now, that's not taking a surgeon's scalpel to the program; that's taking a meat cleaver to the program when you cut it by over half. The acid rain control technology program—at the same time we're politely telling the Canadians we're going to sign a—I don't know whether it's

a treaty; is it a treaty?—it's an agreement of some kind. We're going to sign an agreement with the Canadians in which we agree that we're going to move together into a control technology program. And when the Canadians are pledging that they're going to reduce their production of sulfur dioxide and other pollutants by 50 percent in the next decade, they're giving us specific commitments on control technology capital investment.

Now, let me just add as a footnote to that question—and the question is, Why? The question is, Isn't it a little disingenuous of us, a little bit embarrassingly—I don't like to say "deceitful" about my Government, but wouldn't it be understandable, perhaps, if a foreign observer were to see our Government on the one hand signing an agreement with the Canadians to engage in a control program, and on the other hand cutting its Acid Rain Control Technology Program by over half in 1 year, to the lowest level at which it has ever been, the lowest level in the history of EPA? Isn't there something disingenuous? Wouldn't the foreign observer for the London Times or the Manchester Guardian or the Paris Soir be justified by saying that this is disingenuous and deceitful, and not in—it doesn't show the kind of good faith and bona fides that friendly governments should show toward each other?

I'll give you 12 minutes to think about that. We'll recess for about 12 or 13 minutes.

[Recess.]

Mr. SCHEUER. All right, we will proceed.

Mr. Ehreth.

Mr. EHRETH. Yes, sir. The question is well understood by us, and your assessment of the numbers in the budget is absolutely correct. But we developed our budget, consciously aware of the fact that there is a bill called the Clean Coal Technology Act which, over a period of three years, will provide up to \$400 million in matching funds for the demonstration of clean coal technology.

We have participated in that process inasmuch as we have had people—

Mr. SCHEUER. Excuse me. What percentage of the resources in that act will be applied to the problem of acid rain controls?

Mr. EHRETH. Well, the intent of the Act is to be applied to demonstrating technology for cleaning up coal, whether it's pre-clean the coal or cleaning the stack gases being emitted from the boilers themselves. It's to be applied both, as I recall, to industrial as well as public utilities, public sources of coal-burning power plants.

So—Does that answer that question, sir? Shall I move on?

Mr. SCHEUER. Yes.

Mr. EHRETH. OK. So our research budget, our basic research budget has been fairly constant over the years, and Dr. Skinner can talk to that—

Mr. SCHEUER. But you just cut the research budget by more than half.

Mr. EHRETH. You're right. What you see there is, in fact, the total numbers cut by absolutely half. I say we did that consciously, recognizing the fact that we are now in a demonstration era. If we are to implement the recommendations of the Special Envoys' report, and if that's what the President does next Tuesday—and I have no way of knowing for sure that that's what he will do, but I

read Mr. Shabecoff's article also this morning—assuming that that's what comes out of that process, we are in a demonstration era and we are relying heavily on the Clean Coal Technology Act in demonstrating technology to address SO₂ emissions and NO_x emissions of that nature. So consequently, we did not include in our budget additional moneys for demonstration. We now have on the street the second of two requests for proposals, requests for quotations, to accommodate our demonstrating technology, both for the wall-fired as well as the tangentially fired boilers. The wall-fired boiler is, in fact, a real project now; and groundbreaking, as I recall, will commence in September, this fall. And I talked to the sponsors and I'm sure they would be very interested in having Members of Congress participate in that groundbreaking ceremony. It would be a momentous occasion, no doubt.

In the meantime, the \$5 million that you appropriated for us for the 1986 budget is in the request for proposals on the street for a tangentially fired boiler, and we are now working with the Department of Energy to develop cooperative efforts in funding, if needed, but also we're looking for a shared funding from the private sector and public sector, as well. So that's where we anticipate the money coming from to facilitate that demonstration issue.

In the meantime, if you're interested, we could also describe for you briefly some of the things that we have coming down the pike in the way of new research efforts, and that's what's being funded by the remaining resources that we have in our budget, which is what we call our base research program. Dr. Skinner might be able to—

Mr. SCHEUER. Now, when it comes to the basic research program, we are also there concerned that that has been cut by about 30 percent, your basic research university grants program, where we get the pure research or the basic research that the corporations or engineering schools can then apply.

Now, one of the basic justifications that you give for cutting your basic research is that many other Federal agencies are spending many millions or large amounts of money to support environmental research of all kinds at universities. Can you tell me what other agencies—if this is your justification for cutting basic research, let us know. If that is your explanation, can you tell us what other agencies are funding basic university research on the topic of environment? What are environment outcomes in the incredibly complex business of transport, transformation of dioxins in the environment? What universities are being funded by other agencies to do work in the field of hazardous waste treatment technologies, which is tremendously important?

Mr. EHRETH. OK. That's a little different question than what I was addressing just moments ago. That becomes part of the grand question.

Mr. SCHEUER. Well, if you didn't finish your question, finish your answer. I don't mean to cut you off.

Mr. EHRETH. What I need to explain and clarify was that the word I was using before was our base program as opposed to our basic research program or our "exploratory research program" which you are describing right now.

In our base research program associated with LIMB type technology or, as you termed it, acid rain control technology, we have other innovations in the developmental stage not advanced far enough for demonstration at this point in time. We can talk to you about that if you'd like.

The other issue that you raised, the last issue that you raised, was in regard to our grants and centers program. And you're right, our budget does reflect a decrease of about \$3 or \$4 million in the grants and centers program, which is equivalent to the amount of money that was put into our budget last year by Congress.

Now, with regard to whether or not there are other agencies in town funding that type of research, I'd have to say that the NIEHS or several of the HHS type organizations do fund basic research—

Mr. SCHEUER. For the record, could you spell out that acronym for the benefit of the reporter?

Mr. EHRETH. Yes. National Institute of Environmental Health Sciences, NIEHS. I apologize.

They fund a considerable amount of money for basic research through the university process. In the meantime, we probably are the only agency funding research in the way of engineering technology and monitoring systems, that I know of, at least. If you broaden the definition of ecology and ecological research, you could include in there National Science Foundation, the Forest Service, and probably one or two other organizations also funding ecology-related research. But I think the difference in our program versus the NIEHS Program or the National Science Foundation programs is the focus that we put on our research, and it is focused more toward just those issues that you alluded to a moment ago.

Mr. SCHEUER. How much has their budget been increased?

Mr. EHRETH. I don't have that information. I just don't know.

Mr. SCHEUER. Let me read you a line from the Congressional Research Service.

"A review of related agencies"—agencies related to EPA—"showed that while the National Science Foundation request increases for its research program, other related research programs, including those of the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Oceanic and Atmospheric Administration, and the Department of Energy's energy supply research program could experience decreases if their proposed budgets are adopted"—I presume their approved budgets after they've been through the OMB process.

Do you have any reaction to that?

Mr. EHRETH. No, sir. I don't even know from what you're reading there, to be quite honest with you.

Mr. SCHEUER. All right. That's from a study that the Office of Congressional Research did for us.

All right. I would ask unanimous consent that all Members be—oh, my goodness, there's another roll call—that all Members be permitted to submit additional questions in writing, and we'll hold the record open for another 10 or 12 days to give you time to prepare your answers.

[Material included as appendix p. 231.]

Mr. SCHEUER. Mr. Ehreth, we very much appreciate your testimony. You have been patient and forthcoming, and we again express our admiration and respect to you for the job that you've been trying to do in this interim period. You've been a real trooper, and we admire you and we congratulate you for that.

Mr. EHRETH. Thank you kindly. I appreciate those words.

Mr. SCHEUER. Thank you for your testimony. We have another roll call vote. We will suspend for another 15 minutes, and then we'll be back for the next panel.

[Recess.]

Mr. SCHEUER. The subcommittee will resume.

This panel of leading members of the Health Effects Institute is a real treat, and we're looking forward to it with great pleasure. First of all, I know several of the witnesses from prior reincarnations, and they are very welcome back here. Dr. Kennedy was a superb role model for us all as to what the quintessential Government servant should look like, act like, sound like. Of course, Mr. Cox, Archibald Cox, is a legend in his own time, and will go down in the history books as the exemplar of courage and integrity of those who hold the Constitution above all other mundane happenings in our country. We not only respect you, we revere you for your enormous accomplishments and for the enormous credibility you have given Government, Mr. Cox.

This panel couldn't be more appropriate here today. All of us have been troubled by the institutional problems that have plagued the work of environmental cleanup: the toxic waste controversy, the ground water controversy. We have a truly institutional problem. The genius of American science and technology and the chemical industry and the manufacturing industries have provided bountifully for Americans over the last century, let us say, and certainly over generations past. The saying, "better living through chemistry" is not just a joke; it's true. The chemical industry and certainly our Rust Belt manufacturing industries have provided a bountiful way of life for us which is the envy of the entire world.

A byproduct of that bounty has been the proliferation of toxic wastes, poisons in our ground, in our air, in our water, that society has not so far successfully coped with. The reason that we haven't—one of the major reasons that we haven't coped with it is that Government and industry have been, by and large, been at a standoff. Instead of harnessing the talent that created all this bounty to the job of solving the incidental—not so incidental—toxic effluent of the bounty, and saying, look, your genius created the chemicals; now let your genius create the answers to some of the problems that these chemicals have produced, and the same thing for the manufacturing industry—instead of harnessing the genius of industry to the solution of these problems in tandem with Government, with the regulators, in tandem with the engineering schools and the scientific establishment with industry playing the kind of statesmanlike role that they're capable of playing, and showing the kind of statesmanship that I read all about and heard all about when I was a student at the Harvard Business School more years ago than I care to remember, through the inexorable unfolding of events without pointing the finger of blame anywhere, industry and Government have been at sword's point. There has

developed an adversarial relationship of confrontation that boggles the mind. And as a result, they're spending hundreds of millions of dollars on lawyers' fees to delay Government action, to delay even Government knowledge of the kinds of poisons that they're unleashing in our waters, in our air, on our ground, to delay even the kind of detailed knowledge of the problem that would enable all parties to get together in a civilized way and address these problems constructively.

I'll just give you one classic case of the Dow Chemical Co. in its plant in Midland, MI. The Dow Chemical Co. there has been spewing dioxin into the Tittabawasee River for many, many, many years. And they have successfully defied all efforts of the EPA to find out the hows and the whys and the wherefores of what they're spewing into the Tittabawasee River. They refuse to let the EPA inspectors come into their plant on their grounds. Then they built a great big wall, a great big fence, a 10-foot fence so nobody could peek over and surveil them from the ground. Then the EPA tried testing the waters, and apparently the—if I'm correctly informed—the point at which the effluent, the poisonous effluent coming out of the plant was so far downstream that EPA lawyers were able to establish that—enough doubt remained that other substances from other sources were not involved, and that therefore you couldn't really test what they were doing from the water down there.

So they prevented EPA from testing on the land. They prevented EPA from testing in the water by a whole succession of very clever, very wise, very adroit, very resourceful corporate lawyers who earned their \$350 an hour fees; and then, when EPA hired an airplane to fly over and take surveillance photographs, they sued them, tried to enjoin them from finding out what kind of toxic substances were being released in the air, in the water, on the land. And their counsel, for Dow Chemical—what's the date of this thing?—last December, a few months ago, told the court that EPA's use of aerial photography to investigate possible violations of EPA law and regulations at the plant was "massively intrusive and repugnant." She asserted that "DOW has a right to protect the confidentiality of its business operation" and that "the use of aerial photography ran counter to the company's reasonable expectation of privacy"—privacy about the degree to which Dow Chemical Co., one of the great chemical companies in the world with unparalleled and unrivaled scientific expertise and talent, the degree to which they were spewing their poisons over the landscape, in the air, in the water, on the ground.

Well, if I wrote a fiction novel and the plot unfolded in this way, that first they stopped them on the ground and then they stopped them—they stopped the surveillance on the ground and they stopped the surveillance in the water and then they stopped the surveillance from the heavens, there isn't a publisher in America who would publish it. They would say that it was contrived, that corporations don't act like this, that there's a degree of corporate statesmanship out here, that our institutions of Government wouldn't let the Dow Chemical Co. get away with this outrageous conduct month after month, year after year. Their talented lawyers simply couldn't produce that result of stopping Government dead in its tracks, even to acquiring the basic information as to how,

where, when, and why the Dow Chemical Co. was polluting our planet that we live in, this one little fragile globe. There's not a publisher that would even accept it as credible fiction; but yet, there it is, fact.

Now, without a lot of finger-pointing, how do we get the Dow Chemical Companies of our Nation off of the path of confrontation, off of the path of stonewalling, off of the path of delaying Government processes until the memory of man runneth not, and how do we get them into a cooperative joint effort to solve the problem that they have created as a byproduct of the wonderful products that they have developed that have improved the quality of life for every single one of us? How do we create the environment of good will, and how to create the institutions which will draw them into a cooperative joint effort with Government regulators, with the universities, with the medical schools, perhaps, the great engineering schools, the medical schools—how do we bring them into a joint cooperative effort to solve the problem of the byproducts of their genius?

And I hope that you can tell us something about your experience with the automobile industry and to what—and I hope you will tell us—to what your extent your experience and the systems, the devices, the processes that you have developed would be replicable and susceptible of application to the chemical industries and to the smokestack industries that are causing these awful environmental problems with which Government has not been able to cope. We simply aren't beginning to grapple with the problems.

I could go on for hours telling you about the ground water problems that exist in every single congressional district in the United States. I could tell you about the tens of thousands of toxic waste sites in the United States that we simply don't have the most marginal ability of coping with. I could talk to you about indoor air pollution. I could talk to you about outdoor air pollution, but I think what I've given you is enough to whet your salivary glands.

So with these remarks, I'd be happy to hear your testimony. But before that, of course, I would be happy to recognize Congressman Don Ritter, a very distinguished member of our subcommittee, who has perhaps more scientific background than any of the rest of his colleagues on the subcommittee.

Mr. RITTER. I thank the distinguished chairman for his kind words, and also for his excellent testimony. [Laughter.]

I also would like to welcome a very distinguished panel, and I commend the chairman for putting together this group. Unfortunately, on my list here I have Archibald Cox, Dr. Kennedy, and Dr. Powers, and I don't see Dr. William Baker's name. What happened to our distinguished President Emeritus of the Bell Telephone Laboratories? Somehow we missed him.

Mr. Cox. Initially, he was unable to come. He is here for a short time. We thought he wouldn't be able to join us because of some other very important Government engagements. But he is here—

Mr. RITTER. Well, as someone who has spent a lot of time on the whole issue of health effects as the bottom line as to why and how we regulate, I do welcome this panel. I look forward to your testimony, and I thank the chairman for yielding to me.

Mr. SCHEUER. Mr. Cox, we have to be out of this room, unfortunately, by—they're due to start another hearing here at 1:00 o'clock, so we have to be out of here a minute or two before 1:00. So I'll ask each of you, if possible, to sum up your testimony in about five or six or seven minutes so that we do have some time for questions. All of your prepared testimony will be printed in full at this point in the record.

**STATEMENT OF ARCHIBALD COX, CHAIRMAN, BOARD OF
DIRECTORS, HEALTH EFFECTS INSTITUTE**

Mr. Cox. Thank you, Mr. Chairman. May I also say, on a brief personal note, that I appreciate very much your very generous, warm remarks at the beginning of the hearing. We will assume that the formal introductions have been made and that the statement, as you say, will be part of the record, and I will try to come quickly to the point. Then Dr. Kennedy will testify, and then Dr. Powers.

We all became interested in HEI and are here because of the problem that you rightly called attention to. We have been dealing with it, not in its most difficult sphere but nevertheless in a sphere where it has been disruptive, an impediment to progress. Until the HEI idea was proposed, the standard method, as you know, of developing the science knowledge necessary for regulation was adversarial. The Government agency recruited its scientists; the industry looked askance at that, was worried, rather distrusted it. The industry hired duplicating scientists who then would set out to knock down the Government's scientists. Instead of searching objectively for what is the knowledge and what are the limits on our knowledge, available knowledge, they'd go at it like—I regret to say—a bunch of lawyers. And it involved, also, endless duplication.

We saw—and see—HEI as a special way of bringing industry and Government concerned with regulation to protect the public interest, the public health, bringing them together under independent auspices for the purpose of tapping the best scientific forces and facilities available and personnel available. And in the process, building the kind of spirit that you quite properly said was necessary, to get industry and Government to recognize that they owe all of us common public responsibilities and to think about those and not to think how much they were worried about the adversary. And we think in our area, as far as time has permitted—because research takes a while, and the fruits are just beginning to flow in—but we think thus far, so far as one can see, HEI has not only been a success in the field of science looking to any necessary regulation of the emissions from motor vehicles, but also a model that could be used in other fields.

I think, to try and be brief, that for our role there are essentially four prerequisites, and I suggest to you that those four prerequisites probably exist for a successful model in other areas. One is that the two come together with a heavy third party independent participation. And in our area, at least, we think an important part of that is that HEI's decisions, both as to what the program will be and as to what findings we will make and publicize, will be made by HEI independently. They mustn't be either what the industry

wants or what the Government wants. And we make a major effort to keep in touch with the regulatory needs with EPA, and to be in full consultation as to what their needs are. And equally with what are the needs of the industry because it has some obligations, as you know, under the Clear Air Act. But then when it comes to developing our program of research and to writing the protocols under which research will be done, the shots will be called by HEI independently.

I think a second prerequisite is joint funding in equal shares, or approximately equal shares, from the industry and from the Government. In our case, the shares are equal; the motor vehicle industry, the sellers and distributors of motor vehicles share according to their market shares and EPA puts up the other amount. Currently, our budget is running about \$7 million a year. And that, incidentally, is 50 percent of the research being done in this area in the world at the present time.

Third, we think it's important that either side, either of the sponsors as we think of them, be committed to either staying with us or destroying us. You know, this whole thing has to be built on certain tensions, to be factual about it. And keeping that choice is a way of keeping independence; forcing that choice is a way of keeping independent because EPA can't say, well, we'll fund project A but we won't put up any money for project B; we don't like it. Or the same thing from the industry side.

Then, in our case, we are thoroughly committed, as a fourth prerequisite, to quality science. The main thing is to enlist the best scientists, to assure them the conditions of their independence and the high standards that will attract the best scientists and the best work. In some of the context that you referred to, Mr. Chairman, it may be that the research wouldn't bulk as large. Getting people together to face their responsibilities is important in other contexts; Mr. Powers here knows a good deal about that because he has been thinking about it and is president of Clean Sites, Inc., which has been working in a slightly different format but still to accomplish the kind of objective that you described.

I'll turn it over to Mr. Kennedy in just a moment to describe the scientific program.

We think we have made measurable progress in changing attitudes, particularly among the people who are concerned with the science, the management of their research and their scientific interests, both in industry and in Government and EPA. We have them together, working together. When they get together, it's quite a different atmosphere. You know, when you get people talking about what they have in common you get a different atmosphere, particularly when there are third parties present, than is otherwise the case.

Second, we think that we have reduced the duplication, avoided most of the duplication, and have attracted quality scientists, and therefore science and knowledge, that otherwise couldn't be brought to research for regulatory purposes. The chairman of our research committee, Dr. Walter Rosenblythe—I don't believe either one could enlist the degree of intense interest that he has given to it. Or, for that matter, Dr. Kennedy himself.

And third, we think that this format will result in findings, a base of knowledge, that the public can have more confidence in than if it was science that came from either Government or industry alone.

If I may—and of course, I'll answer your questions later—I think it will be helpful to have Dr. Kennedy outline the scientific program, and Mr. Powers talk briefly about some of the other possibilities we see in the near future.

[Joint prepared statement of Messrs. Cox, Kennedy, and Powers follows:]

Testimony of
Professor Archibald Cox,
Dr. Donald Kennedy
and
Dr. Charles W. Powers
concerning the Health Effects Institute
before
The Subcommittee on Natural Resources,
Agricultural Research and the Environment
Committee on Science and Technology
House of Representatives

March 13, 1986

My name is Archibald Cox, and I am here today in my capacity as Chairman of the Board of Directors of the Health Effects Institute. Accompanying me at the table are two other members of our Board, Dr. Donald Kennedy, the President of Stanford University and former Commissioner of the Food and Drug Administration, and Dr. Charles W. Powers, President of Clean Sites, Inc., a non-profit corporation dedicated to accelerating the private cleanup of hazardous waste sites in the United States, and the founding Executive Director of the Health Effects Institute. Our fourth Board member, Dr. William O. Baker, President emeritus of Bell Laboratories, extends his apologies for being unable to appear with us today.

The Health Effects Institute is an important new step in the conduct of the environmental science that must underlie public regulation, one that I believe to be enthusiastically supported by the leadership of the Environmental Protection Agency and the managements of those industrial companies that make and market motor vehicles or their engines in the United States. The Institute is a unique way of bringing government and an industry together to tap, under independent auspices, the best scientific talent available at our universities and research institutes and so to provide the kind of scientific base for government regulations in which the public can have confidence - here the

regulation necessary to safeguard the public health from any dangerous emissions from motor vehicles. We believe that HEI will be a model for joint government - industry cooperation in attacking mixed problems of science and regulation in other fields. In our remarks today, we will describe (1) the genesis of the Institute and our participation, (2) the current governance structure and funding, (3) the broad outlines of the scientific program, and (4) some other areas in which the HEI model might be useful.

I. The Genesis of HEI

I can describe the origins of HEI best by explaining how I came to be interested. As a lawyer in and on the fringes of government, I knew that proposals for government regulation of industry to protect the public health and safety all too often produced bitter disputes about the knowledge of scientific data conclusions at their base. Leaving the search for knowledge concerning the health effects of possibly harmful substances to the adversarial process engaged percommitted experts on each side as each attempts to use science to advance its interests. The process not only wastes scarce resources, but subverts the purposes of science and obscures the real social policy differences that ought to be thoroughly debated. Often the best scientists simply refuse to participate. Often still worse, total resort to the adversarial process obscures the fact that government agencies and the industry share common interests and

responsibilities that they should join in recognizing - common interests and responsibilities not only in good science but in the public health.

Consequently, I was greatly interested when invited by then EPA Administrator Douglas Costle, and encouraged by William Ruckelshaus, when he was in the private sector, to serve as a Director of the new organization -- now the Health Effects Institute - that EPA and the motor vehicle manufacturers were hoping to work out, dedicated to quality science in regulation and to building bridges between the public and private sectors. Mr. Powers had been a central figure. President Kennedy of Stanford joined, and later Mr. Baker. All of us, and the others involved in the foundation, thought it essential that this new Institute be built in such a way that it would be truly independent and thus credible and accountable to the public.

II. The Unique HEI Governance and Funding Structure

To achieve that there had to be agreement upon four points. HEI's principal governance and funding structures grew from them:

- o HEI must be truly independent in governance - free to make its own decisions in developing not only the general program of research but the specific grants and protocols. In order to ensure relevance to potential regulatory needs, we would regularly consult the sponsors and other interested groups, such

as environmental organizations; but we would then make our own decisions. Similarly, our findings would be published without prior clearance by either industry or government.

- o HEI must have financial support from both government and industry, so that both government and industry would have a stake in the venture, so that we would have incentive to listen to both but bow to neither, and so that the public could have confidence in our findings about health effects.

- o Both industry and government must either support the Institute or destroy it. There could be no veto of particular undertakings or segments of research.

- o HEI must be dedicated to quality science from definition through review: The new institution must be structured to define, select, support and review research to promote the application of the best science to the possible effects of mobile source emissions.

Senior management in both government and industry took the challenges seriously and gave assurances upon these points. Funding is provided on a fifty-fifty basis by the Environmental Protection Agency and twenty-five manufacturers of cars, trucks, and engines who market in the United States. The manufacturers and the EPA under successive administrators have committed themselves to the belief that they can rely upon HEI as the major

source of studies on the health effects of motor vehicle emissions in this country. At present, the Institute has a budget of about \$7 Million dollars annually, and it accounts for nearly 50% of all the research done on these issues in the industrialized world, including Japan and Europe.

With your permission, Mr. Chairman, I shall turn over to Dr. Kennedy the discussion of the HEI scientific program. Before I do that, however, I want to emphasize the benefits of this mode of programming regulatory research. It has the obvious benefit of reducing the overall amount of money that must be spent by society on research. Not only does the taxpayer receive two dollars of research for every federal dollar expended, but the money is not spent in an adversarial fashion with unnecessary duplication. No longer do we have government research programs that industry suspects are aimed at justifying regulations and industrial research programs applying more money in a defensive fashion. Scientist participate who would not work for government or industry alone. We also are developing a common fact base upon which policy decision can be debated. The joint and equal funding of the Institution, as well as its mode of governance, enhances the probability of public acceptance of the science because there are no incentives for systematic bias. Ultimately, our program has to meet the true needs of both the public and the

private sectors; if we satisfy only one or neither, we fail and will cease to exist. Our funding and governance structure, therefore, creates a controlling incentive to engage the very best scientific resources and to call the shots solely as we see them.

III. The HEI Scientific Program

Mr. Chairman, HEI actually has been sponsoring research only since the summer of 1983. The prior time was spent in a very careful effort to put together the best possible scientific panels, to develop a scientific funding process that would earn scientific and public confidence, and recruit a small but outstanding scientific staff.

HEI currently has about 50 studies underway with principal investigators at 35 research institutions in the United States. It also sponsors, with its industrial funds, several studies at institutions in West Germany, Canada and the United Kingdom. These studies are oriented toward providing the scientific underpinning necessary for rational decisionmaking with respect to the National Ambient Air Quality pollutants, Nitrogen Dioxide, Ozone, Carbon Monoxide and Diesel Particulate. The Institute is also sponsoring studies to ensure that future technology does not pose unreasonable risks to the public health. In particular, the Institute is investigating the effects that new fuel mixtures might have on levels of pollutants such as formaldehyde.

HEI's Research Committee, a distinguished group of scientists chaired by the current foreign secretary of the

National Academy of Sciences and former provost of MIT, Walter Rosenblith, prepares the research program for submission to the Board of Directors and supervises the award of contracts for specific research. The Committee entered the air pollution problem in midcourse, after our society had more than a decade of experience with living under the demands of the Clean Air Act. In setting the original National Ambient Air Quality Standards, the Congress had necessarily made policy judgments regarding standards, sometimes in the absence of a well developed scientific base. In tackling a highly contentious area of science, our Research Committee recommended, and we agreed, that we try to do research in a way that increased our understanding of what was happening as emissions left the tailpipe, interacted with the atmosphere, entered the human pathways, and finally reached the human organs of particular concern. In response to this rough flow diagram, and to the inherent problems of all modes of research in the environmental sciences (whether they be animal toxicology, in vitro studies, epidemiology or human clinical experiments), the Institute has shaped a program that attempts to build both a broad scientific base, as well as to address near-term regulatory problems. Indeed, it is, in part, in the attempt to merge regulatory relevance with the development of an up-to-date scientific base that we hope to show that HEI is different.

To implement a strategy of combining new principles with old problems, HEI has chosen to use the scientific equivalent of the

"free market." We define problems that are of both regulatory and scientific importance, and then leave it to the research community to respond in a competitive fashion by making specific, detailed proposals for research projects. We carefully review the applications with respect to both scientific merit and regulatory relevance and fund about 15% of the applications we receive. Through this process, we have been able to attract a number of first class investigators into this area who did not work in it before.

Our current work is exemplified by a number of different projects, immediately relevant to regulation, including:

- o A multi-center study of the health effects of low levels of carbon monoxide on patients with heart disease. This set of studies is being conducted in response to a major problem encountered by the government in interpreting prior studies, some of which may have been fraudulent. The current HEI study will be directly relevant to the next standard-setting process for CO.

- o A set of studies on Nitrogen Dioxide, conducted in different clinical settings, on different kinds of patient populations, to determine whether particular susceptible populations exist. This determination of susceptibility is important because of the requirements of the Clean Air Act to set standards to protect sensitive populations.

o A set of wide-ranging studies on the health effects of diesel particulates. Taken together with animal toxicology that was commissioned around the world before HEI was established, this work may have a significant effect on future EPA regulation.

o An evaluation of the health effects of gasoline vapors, conducted in order to assist EPA and the industry in clarifying the uncertainties in the existing data base.

A unique element of HEI is embodied in its scientific evaluation function. Once research is completed, it is subjected to an intensive peer review by the Institute's Review Committee, which had no role in selecting, shaping, or monitoring the project. This Committee, which is chaired by Dr. Robert Levy, Professor of Medicine at Columbia University and former Director of the National Heart, Lung and Blood Institute, develops a technical evaluation of the project, which is published along with the scientific report of the investigator and a message from the Board of Directors. The report is designed to clarify findings, particularly for the non-scientific decision maker, and to provide a comparative assessment among research projects in a particular area.

I would now like to turn the discussion briefly over to Dr. Powers to discuss some of the broader ramifications of the HEI model, as a prelude to answering your questions.

IV. Evaluating Success and New Problems

We believe that it is still too early to say definitively whether HEI is a success, but the signs are promising. No one questions the independence and integrity of the organization, nor is there any quarrel with the quality of the science. We have already encountered an issue-- gasoline vapors -- in which a report of the Institute tended to question the strongly held beliefs of some members of the sponsor community. In that environment, we have managed to maintain the support of all of the sponsors, particularly at the senior management level. Our program is responsive to sponsor needs, while maintaining an independent understanding of what good science demands. Perhaps most importantly, we have demonstrated the possibility of developing a community of interest among scientists and non-scientists, where previously animosity predominated.

To be sure, there are still tensions -- mostly constructive -- in finding a working definition of "relevance" that scientists, and those concerned with near term decisions agree to and are comfortable with. And there are still people, in all sectors of our society, who find it in their interest to continue battles, rather than to find ways to ameliorate conflict.

Given this overall picture, we believe that there are significant other opportunities for using the HEI model. Without going into them in depth, they include:

- o Problems of indoor air pollution:

Evidence continues to mount that air pollution is a problem indoors (for example, in residences, schools, offices, commercial and public buildings) as well as out. Studies have documented an indoor buildup of toxic and carcinogenic emissions from passive tobacco smoke, unvented gas-fired appliances, building materials, furnishings, consumer products, and underlying soil. The relative risks of indoor, as opposed to out-door, air pollution for individuals and populations are not well defined. Yet, adverse health consequences from indoor exposures are a potentially serious public health problem of enormous dimensions. This emerging environmental health issue offers an opportunity for industry-government cooperation to define the extent and magnitude of the problem, and to design appropriate control strategies. Application of the HEI concept to indoor air quality issues appears to be a logical and natural outgrowth HEI's mission.

o The Risks of Toxic Air Pollutants:

The fear generated by both the Bhopal situation and the Institute, West Virginia leak emphasizes again the necessity for a credible scientific institution that can systematically evaluate the risks of many chemicals. We believe that an organization like HEI could make a major impact on the chemical evaluation problem.

Every policy problem presents its own particular set of dynamics. Among the many lessons we learned in the establishment of HEI is that cooperation is not easy. Substantial efforts must be made to provide the resources and the organizational catalysts that will be necessary to stimulate these kinds of public-private-university organizations. It is, however, possible to succeed, if the right group of people is attracted to a credible and independent institution. Success is also only possible in an environment in which the government itself has a strong scientific program. Organizations like HEI can most effectively complement the internal research apparatus of regulatory agencies; they should not simply supplant them. EPA must continue to have its own cadre of skilled scientists to interact with the broader scientific community, to perform and evaluate work in short-term time frames, and to provide sound advice to decisionmakers.

V. The Importance of the HEI Experiment

In closing, Mr. Chairman, we want to emphasize again the importance of the HEI experiment in the context of overall research and development policy in the 1980's. A period of very tight resources looms in front of us, as we struggle with the budget. In the Health Effects Institute, we are testing a model that has wide applicability both within and without regulatory science. If our nation's scientific and technological base is to continue to fuel our economy, we must find ways for industry and

government to collaborate effectively and to pool research resources. Many people talk about industrial-governmental collaboration. The EPA, the automobile industry, and a major piece of the scientific community are doing something about it. The concept behind HEI, and the institution itself, deserve the Federal government's support, in FY 1987 and beyond.

With your permission, Mr. Chairman, we attaching a copy of the HEI bylaws to our testimony, so that the Committees can see how we are currently structured, as well as a copy of our most recent Annual Report, which contains detailed scientific and financial information about the Institute.

Thank you for your attention, and we'd be please to answer any questions.

Mr. SCHEUER. Very good. Thank you very, very much, Mr. Cox, and I'm sure we'll have some questions to you.

And for all of you, as you talk, if you could give us some hint as the testimony develops as to whether the techniques that you've developed and the systems and whatnot would be applicable to the chemical industries and the smokestack industries, the major utilities, the major manufacturers. That would be extremely helpful to us.

We welcome you back here, Dr. Kennedy.

STATEMENT OF DR. DONALD KENNEDY, PRESIDENT, STANFORD UNIVERSITY AND MEMBER, BOARD OF DIRECTORS, HEALTH EFFECTS INSTITUTE

Dr. KENNEDY. Mr. Chairman, it's a pleasure to be with you again.

I want to just briefly sketch the scientific program and some of the features that we see in it that are special and might be applicable elsewhere, as you suggest.

We've been sponsoring research only since the summer of 1983. Three studies, I think, are now complete so it's a short track record to judge us on, but we have a very substantial program out there now; 50 studies underway at 35 research institutions, including participation from really first-rate places. I think Dr. Baker would agree with me that our capacity to attract the best scientists and to get them involved in this project has been really remarkable and very gratifying.

We are not limited to meeting immediately existing requirements. We are trying to step ahead and to anticipate. For example, we are looking at new ways of DNA adducts, recombinant DNA techniques in providing tests for the health hazards posed by pollutants. So methodology development is part of it; so is an investigation of the effects that new fuel mixtures might have on levels of such pollutants as formaldehyde.

The program is under the direction of a research committee of which, as Professor Cox just told you, Walter Rosenblythe, the former Provost at MIT and former Secretary of the National Academy of Sciences has agreed to act as chairman and has been doing so very successfully. It's a distinguished group. The research committee has agreed that we ought to try to do research in a way that flows naturally through the stages of the problem, beginning with what happens when emissions leave the tailpipe, what happens when they interact with the atmosphere, how they enter human pathways, and finally, how they reach the organs of real concern. We have, I think, been able to classify the problems and approach them in a systematic way using both in vitro studies, epidemiology, classical toxicology, and human clinical experiments, and we've been able to shape a program that draws on all those disciplinary domains and involves, as I said before, good people and good institutions.

We try to define problems that are of both regulatory and scientific importance and to leave it to the research community to respond in a competitive fashion. Those responses have been extensive and gratifying, both in numbers and quality. We find ourselves

able to fund about 15 percent of the applications we receive and that, I think, is a good quality subset of what we invite.

Just briefly I'll tick off some of the areas.

We have a multicenter study on the health effects of low levels of carbon monoxide on patients with heart disease. A very important issue required clarification in that area; ambiguous, somewhat doubtful previous studies, and a distinctive need for clarification—that will be relevant to the next standards-setting process for carbon monoxide.

A series of studies on nitrogen dioxide in different clinical settings on different kinds of patient populations to enable HEI to help us respond to the requirement that we set quality standards for sensitive populations.

A set of wide-ranging studies on the health effects of diesel particulates and evaluation of the health effects of gasoline vapors; and, in addition, a variety of studies that are focused on methods development and on longer range problems.

I want to briefly mention the scientific evaluation function.

One of the difficulties that I experienced as head of a regulatory agency was that for the work that we would commission or that would be offered to us by industry, there wasn't a systematic process for third-party peer review. We've built that into the system. There's a review committee that perform that function, and it is a group of scientists that had no role in selecting or shaping or monitoring the program. It gets the work product *de novo*, the way an editorial board of a journal would; only, the level of review that it's able and willing to apply to the problem is substantially more intense. That committee is chaired by Bob Levy, the former Director of the National Heart, Lung, and Blood Institute, now professor of medicine at Columbia University.

The peer review reports are published together with the scientific report of the project; and that, we think, will help clarify for the nonscientific decisionmaker what kind of assessment he or she can place on the validity of those scientific findings for whatever public policy purpose the agency has responsibility for.

Now, let me turn to Chuck Powers for a discussion of some of the model possibilities of the Health Effects Institute.

STATEMENT OF CHARLES W. POWERS, PRESIDENT, CLEAN SITES, INC., AND MEMBER AND FOUNDING EXECUTIVE DIRECTOR, BOARD OF DIRECTORS, HEALTH EFFECTS INSTITUTE

Mr. POWERS. Thank you, Don.

Again, we have to say that it is too early to definitively determine whether HEI is a success; but, as we've said, the signs are promising. I think the most exciting thing is that no one questions today either the independence or the integrity of the organization, nor is there any question about the quality of its science. An organization as young as this having achieved that, we think is remarkable. That's not to say that there are not still tensions—mostly constructive—in trying to find a working definition of "relevance" that scientists and those concerned with near term decisions—

Mr. SCHEUER. A working definition of what?

Mr. POWERS. Relevance.

Mr. SCHEUER. Relevance?

Mr. POWERS. Relevance.

It would be anticipated to be a major struggle as an organization tried to work between industry and Government in this area.

But I think that the fact that there is a scientific community of this quality now actually at work has made that question a scientific question and no longer one that is reduced to winds of change.

You've questioned how this institution functioned since it was created, and let me go back and spend a minute. We have managed to maintain the support of all of the sponsors, particularly at the senior management level. Both the Government and the industry—and I believe in any similar enterprise, other interested institutional leadership—must be involved in the formation of an institution like this, and they must be able, by virtue of their commitment to it, to draw to this kind of enterprise the kind of leadership that Professor Cox and Doctors Kennedy and Baker bring to this kind of enterprise.

To be sure, not everything is known about how this can work in other contexts, but after this overall picture, let me take several other areas in which we think this could become a model.

In the problems of indoor air pollution, there is no question but what there are adverse health consequences from indoor exposures and that they are, potentially at least, serious public health problems of enormous dimensions. This emerging environmental health issue offers an opportunity here for industry and Government cooperation involving a variety of industries to define the extent and magnitude of the problem, and to design appropriate control strategies.

In terms of the risks of toxic air pollutants, concerns well-publicized concerning industrial leaks, it emphasizes again the necessity for a credible scientific institution that can scientifically and systematically evaluate the risks of the many chemicals which are of concern. And we believe that an organization like HEI could make a major impact on the chemical evaluation problem.

Among the lessons we have learned in the establishment of HEI is that cooperation is never easy. It takes that leadership to be able to create the context in which that cooperation can then be followed out by the members of those other institutions. Substantial efforts must be made to provide the resources and the organizational catalysts that will be necessary to stimulate this kind of public/private university organization. It is, however, possible to succeed if the right group of people is attracted to such an institution, and success is only possible in an environment in which Government itself has a strong scientific program. And let me emphasize that. It is only possible where Government itself maintains the capability to translate what is going on in the enterprise that is now independently developing into scientific results. Organizations like HEI can most effectively complement the internal research apparatus of regulatory agencies. They should not simply supplant them. EPA must continue to have its own cadre of skilled scientists to interact with the broader scientific community to perform and evaluate work in short-term timeframes and to provide sound advice to those who must make regulatory decisions.

In closing, Mr. Chairman, we want to emphasize again the importance of the HEI experiment in the context of the overall research and development policy in the 1980's, a period of very tight resources in front of us as we struggle with the budget. In the Health Effects Institute we are testing a model that has wide applicability, both within and without regulatory science. If our Nation's scientific and technological base is to continue to fuel our economy, we have to find ways for industry and Government to collaborate. Many people talk about industrial/governmental collaboration. The EPA, the automotive industry, and a major piece of the scientific community are now doing something about it. The concept behind HEI and the institution itself deserve the Federal Government's support in 1987 and beyond.

With your permission, Mr. Chairman, we are attaching a copy of the HEI bylaws to our testimony so that the committee may see how we are currently structured, as well as a copy of our most recent annual report.

[Material referred to follows:]

BY-LAWS OF THE
HEALTH EFFECTS INSTITUTE

ARTICLE I

NAME

The name of the corporation shall be The Health Effects Institute (hereinafter, "the Institute").

ARTICLE 2

PURPOSES

The purposes for which the Institute is formed and for which it shall operate are as set forth in Article III of the Articles of Incorporation, as amended from time to time. The Institute shall be a non-profit corporation, and shall not have capital stock, shareholders, or members.

ARTICLE 3

OFFICES

The principal office of the Institute shall be located in Cambridge, Massachusetts, and the Institute may have such other offices within or without the District of Columbia as the Board

of Directors may from time to time establish.

The operations of the Institute shall be conducted within the territorial limits of the United States and at such other place or places as the Board of Directors may determine.

ARTICLE 4

BOARD OF DIRECTORS

Section 1. Membership. The Board of Directors shall be composed of three persons, none of whom shall serve simultaneously as a member of the Health Research Committee or the Health Review Committee. No person may serve on the Board of Directors (a) who is employed by or otherwise regularly receives compensation from any governmental agency whose primary responsibility is protection of the environment or the regulation of motor vehicles, or (b) who is an officer, director, agent, or employee of, or otherwise regularly receives compensation from, any corporation or other entity that manufactures, assembles, or distributes automobiles, trucks or other motor vehicles or engines for motor vehicles (such corporations and entities hereinafter to be referred to as "members of the motor vehicle industry"), or (c) whom the Board finds to have demonstrated, by affiliation or conduct, a lack of objectivity relating to the health effects of motor vehicle emissions. Directors need not be residents of the District of Columbia.

Section 2. Selection. The initial Board of Directors shall consist of the persons named in the Articles of Incorporation. As vacancies occur on the Board, new members shall be selected by the remaining members of the Board, after inviting recommendations from the Administrator of the Environmental Protection Agency, other governmental agencies whose primary responsibility is protection of the environment, members of the motor vehicle industry, organizations active in the field of health effects of motor vehicle emissions, and other interested members of the public. In the event that there are no members of the Board available to select new members of the Board, former members of the Board who would still be eligible to serve on the Board under Section 1 shall be eligible (as if they were current members) to participate in the selection of three new members. In the event that the former members of the Board available to select new members are fewer than two, the Administrator of the Environmental Protection Agency shall participate, as if he or she were a current member, in the selection of new members. The selection of any person to be a Director shall be subject to approval by the Administrator of the Environmental Protection Agency and by a majority of the members of the motor vehicle industry who contribute funds to the Institute.

Section 3. Term of Office and Removal. Members of the Board of Directors shall serve for six years or until their successors are elected and qualified, except that in the case of the initial Board of Directors William O. Baker shall serve for

two years, Archibald Cox for four years, and Donald Kennedy for six years. A Director elected to fill the unexpired term of another Director shall serve the remainder of such unexpired term. A Director may be removed at any time by the Board whenever, in the judgment of the Board, the best interests of the Institute would be served thereby; and any such decision by the Board shall be final and conclusive. A Director may be re-elected at the conclusion of his or her term, without restriction on the total number of terms served.

Section. 4. Chairman. The Board of Directors shall elect one member to serve as Chairman. The Board may elect another member to serve as Acting Chairman during the absence of the Chairman. The term of office of the Chairman shall be one year. The Chairman may be re-elected at the conclusion of his or her term, without restriction on the total number of terms served.

Section 5. Functions. The Board of Directors shall conduct the affairs and manage the property of the Institute. The Board of Directors shall have the authority to do all things necessary or convenient, and not otherwise prohibited by the Articles of Incorporation or the laws of the District of Columbia, to carry out the purposes of the Institute. In particular, the Board of Directors shall assure the financial integrity of the Institute; shall adopt the Institute's budget and assure that the Institute's activities conform to the budget; shall select the

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members of the Health Research Committee and the Health Review Committee and the officers of the Institute; and shall have authority to disapprove the award of any contract by the Health Research Committee and the selection by the officers of the Institute of other employees or any consultants, accountants or counsel to the Institute; and shall generally assure that the activities of the Institute conform to its purposes as set forth in the Articles of Incorporation and comply with the requirements of the Federal Internal Revenue Code, as amended from time to time, for treatment as a tax-exempt organization.

ARTICLE 5
MEETINGS OF THE BOARD OF DIRECTORS

Section 1. Regular Meetings. Regular meetings of the Board of Directors may be held at such times and places, within or without the District of Columbia, as shall be determined, from time to time, by a majority of the Directors, except that at least one such meeting, to be known as the Annual Meeting, shall be held each year on a date occurring between February 1 and April 1, at which meeting the Annual Report for submission to the District of Columbia Recorder of Deeds shall be adopted. Failure to hold the Annual Meeting during the period designated shall not work a dissolution of the Institute. The Chairman shall direct the Secretary to give written notice of the time and place of a regular meeting and the agenda of items to be considered at such meeting to each Director at least ten (10) days prior to the day named for the meeting. The notice required by this section may be waived by a unanimous vote of all the Directors, and items may be added to the agenda of a regular meeting without notice by a unanimous vote of all the Directors.

Section 2. Special Meetings. Special meetings of the Board of Directors may be called by the Chairman on three (3) days' written notice to each Director, which notice shall state the time, place, and purpose of the meeting, and an agenda of the items to be considered at the meeting. The Chairman shall direct the calling of a special meeting, with such notice, on the

request of any two Directors. The notice required by this section may be waived by a unanimous vote of all the Directors, and items may be added to the agenda of a special meeting by a unanimous vote of all the Directors.

Section 3. Quorum. At all meetings of the Board of Directors, two Directors present in person or by telephone shall constitute a quorum for the transaction of business; and an act of a majority of the Directors present at a meeting having a quorum shall be an act of the Board of Directors. If at any meeting of the Board of Directors, less than a quorum is present, the Director present may adjourn the meeting from time to time; and any business that might have been transacted at the meeting as originally called may be transacted without further notice at the reconvened meeting, a quorum being present.

Section 4. Meetings by Conference Call. Any meeting of the Board of Directors, except the Annual Meeting, may be held by conference call.

Section 5. Unanimous Consent. Unless otherwise restricted by the Articles of Incorporation or these by-laws, any action required or permitted to be taken at any meeting of the Board of Directors may be taken without a meeting if all the Directors consent thereto in writing and the writing or writings are filed with the minutes of the proceedings of the Board of Directors.

Section 6. Minutes. Minutes shall be taken of all meetings of the Board of Directors, and the outcome of all votes taken at such meetings shall be recorded in the minutes.

ARTICLE 6

HEALTH RESEARCH COMMITTEE

Section 1. Membership. The Health Research Committee shall consist of not fewer than six nor more than nine persons, each of whom shall be eminent in a scientific or medical field. The members of the Health Research Committee collectively shall have training and experience in the principal scientific competencies relevant to the conduct of research on the health effects of motor vehicle emissions. No member of the Health Research Committee may, while serving on such Committee, also serve on the Health Review Committee. No person may serve on the Health Research Committee (a) who is employed by any governmental agency whose primary responsibility is protection of the environment or the regulation of motor vehicles, or (b) who is an officer, director, agent, or employee of any corporation or other entity that manufactures, assembles, or distributes automobiles, trucks or other motor vehicles or engines for motor vehicles, or (c) whom the Board of Directors finds to have demonstrated, by affiliation or conduct, a lack of objectivity relating to the health effects of motor vehicle emissions.

Section 2. Selection. The members of the Health Research Committee shall be appointed by the Board of Directors after inviting recommendations from the Administrator of the Environmental Protection Agency, other governmental agencies whose primary responsibility is protection of the environment, the President of the Institute of Medicine of the National Academy of Sciences, the members of the motor vehicle industry, organizations active in the field of health effects of motor vehicle emissions, and other interested members of the public. Vacancies on the Health Research Committee shall be filled in the same manner.

Section 3. Term of Office and Removal. The term of office of members of the Health Research Committee shall be three (3) years or until their successors have been appointed and qualified, except that, as nearly as possible, one-third of the membership of the initial Health Research Committee shall serve for one year, one-third shall serve for two years, and one-third shall serve for three years. The designation of who among the initial members of the Health Research Committee shall serve for each of these terms shall be made by the Board of Directors. A member of the Health Research Committee may be removed from office at any time by the Board of Directors whenever, in the judgment of the Board of Directors, the best interests of the Institute would be served thereby; and any such decision by the Board of Directors shall be final and conclusive. A member of the Health Research Committee may be reappointed at the

conclusion of his or her term, without restriction on the total number of terms served.

Section 4. Chairman. The Board of Directors shall appoint one member of the Health Research Committee to serve as Chairman. The Board may appoint another member to serve as Acting Chairman during the absence of the Chairman. The term of office of the Chairman shall be one year. The Chairman may be reappointed at the conclusion of his or her term, without restriction on the total number of terms served. The Board of Directors may at any time remove a member of the Health Research Committee from the chairmanship whenever, in the judgment of the Board of Directors, the best interests of the Institute would be served thereby; and any such decision by the Board of Directors shall be final and conclusive.

Section 5. Functions.

(a) The Health Research Committee shall recommend to the Board of Directors priorities for research concerning the health effects of motor vehicle emissions, a research program, and a biennial research budget. Such priorities, research program, and budget shall become effective when approved by the Board. The Health Research Committee may recommend modifications in the priorities, research program and budget from time to time, as it finds necessary or desirable; and such modifications shall become effective when approved by the Board of Directors. The Board may

make such modifications on its own initiative. In performing its functions, the Committee shall invite recommendations from the Environmental Protection Agency, other governmental agencies whose primary responsibility is protection of the environment, members of the motor vehicle industry, organizations active in the field of health effects of motor vehicle emissions, the scientific community, and other interested members of the public. Any research program adopted by the Board of Directors shall be made available on request to the Environmental Protection Agency, other governmental agencies whose primary responsibility is protection of the environment, members of the motor vehicle industry, organizations active in the field of health effects of motor vehicle emissions, the scientific community, and other interested members of the public.

(b) The Health Research Committee shall be the repository for data and other information submitted by members of the motor vehicle industry.

(c) In accordance with the research program and the budget, the Health Research Committee shall authorize the conduct of specific studies and, subject to Article 4, Section 5, shall have authority to make grants to, or enter into contracts with, outside scientific institutions or scientists for such studies. The Committee may not, without the express approval of the Board of Directors, (i) make a grant to, or contract with, a member of the Committee or of the Health Review Committee or (ii) make a

grant or contract for a study for which such a member will be the principal investigator.

(d) The Health Research Committee may request members of the motor vehicle industry, as appropriate, to undertake studies to identify suspect pollutants in emissions and/or to gather exhaust samples necessary to conduct further studies of such pollutants. In so doing, the Committee shall, to the extent possible, assure that burdens it asks members of the industry to assume are distributed fairly.

(e) To help it in the performance of its functions (and in particular to make available expertise not present in the Committee and to assure access to a diversity of scientific views), the Committee may, with the approval of the Board, establish temporary task forces composed of outside scientists with the relevant expertise. These task forces will be advisory to the Committee.

(f) After the first year of its operation, the Committee may, after inviting recommendations from the Environmental Protection Agency, other governmental agencies whose primary responsibility is protection of the environment, the members of the motor vehicle industry, organizations active in the field of health effects of motor vehicle emissions, the scientific community, and interested members of the public, propose for the succeeding budget period such other research activities as are

necessary or desirable to improve scientific understanding of the relationship between motor vehicle emissions and public health.

ARTICLE 7

MEETINGS OF THE HEALTH RESEARCH COMMITTEE

Section 1. Meetings. Meetings of the Health Research Committee may be held at such times and places as shall be determined, from time to time, by the Committee. The Chairman of the Committee shall direct the Secretary of the Institute to give written notice of the time and place of a meeting and the agenda of items to be considered at such meeting to each member of the Committee at least ten (10) days prior to the day named for the meeting. The notice required by this section may be waived by a unanimous vote of all the members of the Committee, and items may be added to the agenda of a meeting without notice by a unanimous vote of all the members.

Section 2. Quorum. At all meetings of the Health Research Committee, a quorum for the transaction of business shall consist of a majority of the entire Committee, and each member present in person or by telephone shall be counted toward the quorum. An act of a majority of the members of the Committee present at a meeting having a quorum shall be an act of the Committee. If at any meeting of the Committee less than a quorum is present, the Chairman may adjourn the meeting from time to time; and any

business that might have been transacted at the meeting as originally called may be transacted without further notice at the reconvened meeting, a quorum being present.

Section 3. Meetings by Conference Call. Any meeting of the Health Research Committee may be held by conference call.

Section 4. Unanimous Consent. Unless otherwise restricted by the Articles of Incorporation or these by-laws, any action required or permitted to be taken at any meeting of the Health Research Committee may be taken without a meeting if all the members of the Committee consent thereto in writing and the writing or writings are filed with the minutes of the proceedings of the Committee.

Section 5. Minutes. Minutes shall be taken at all meetings of the Health Research Committee, and the outcome of all votes taken at such meetings shall be recorded in the minutes.

ARTICLE 8

HEALTH REVIEW COMMITTEE

Section 1. Membership. The Health Review Committee shall be composed of five persons, each of whom shall be eminent in a scientific or medical field. The members of the Committee collectively shall have training and experience in the principal

scientific competencies relevant to the review of research on the health effects of motor vehicle emissions. No member of the Committee may, while serving on such Committee, also serve on the Health Research Committee. No person may serve on the Health Review Committee (a) who is employed by any governmental agency whose primary responsibility is protection of the environment or the regulation of motor vehicles, or (b) who is an officer, director, agent or employee of any corporation or other entity that manufactures, assembles, or distributes automobiles, trucks, or other motor vehicles or engines for motor vehicles, or (c) whom the Board of Directors finds to have demonstrated, by affiliation or conduct, a lack of objectivity relating to the health effects of motor vehicle emissions.

Section 2. Selection. The members of the Health Review Committee shall be appointed by the Board of Directors after inviting recommendations from the Administrator of the Environmental Protection Agency, other governmental agencies whose primary responsibility is protection of the environment, the President of the Institute of Medicine of the National Academy of Sciences, the members of the motor vehicle industry, organizations active in the field of health effects of motor vehicle emissions, and other interested members of the public. Vacancies on the Health Review Committee shall be filled in the same manner.

Section 3. Term of Office and Removal. The term of office of members of the Health Review Committee shall be three (3) years or until their successors have been appointed and qualified, except that, as nearly as possible, one-third of the membership of the initial Health Review Committee shall serve for one year, one-third shall serve for two years, and one-third shall serve for three years. The designation of who among the initial members of the Health Review Committee shall serve for each of these terms shall be made by the Board of Directors. A member of the Health Review Committee may be removed from office at any time by the Board of Directors whenever, in the judgment of the Board of Directors, the best interests of the Institute would be served thereby; and any such decision by the Board of Directors shall be final and conclusive. A member of the Health Review Committee may be reappointed at the conclusion of his or her term, without restriction on the total number of terms served.

Section 4. Chairman. The Board of Directors shall appoint one member of the Health Review Committee to serve as Chairman. The Board may appoint another member to serve as Acting Chairman during the absence of the Chairman. The term of office of the Chairman shall be one year. The Chairman may be reappointed at the conclusion of his or her term, without restriction on the total number of terms served. The Board of Directors may at any time remove a member of the Health Review Committee from the chairmanship whenever, in the judgment of the Board of Directors,

the best interests of the Institute would be served thereby; and any such decision by the Board of Directors shall be final and conclusive.

Section 5. Functions. The Health Review Committee shall assure adequate quality control of studies funded by the Institute, and shall review reports and audits of such studies, and, in its discretion, data from such studies; and with respect to each such study shall prepare a written review containing its opinions concerning the adequacy of the protocol, the conduct of the study, the results of the study, and any other scientific aspects of the study relevant to an evaluation of the conclusions to be drawn from the study. To aid it in the review of studies, the Committee may, with the approval of the Board of Directors, establish temporary subcommittees of outside scientists with relevant expertise when the subject matter of studies makes necessary the application of expertise not present within the Committee.

ARTICLE 9

MEETINGS OF HEALTH REVIEW COMMITTEE

Section 1. Meetings. Meetings of the Health Review Committee may be held at such times and places as shall be determined, from time to time, by the Committee. The Chairman of the Committee shall direct the Secretary of the Institute to give

written notice of the time and place of a meeting and the agenda of items to be considered at such meeting to each member of the Committee at least ten (10) days prior to the day named for the meeting. The requirement for notice of a meeting may be waived by a unanimous vote of all the members of the Committee, and items may be added to the agenda of a meeting without notice by a unanimous vote of all the members.

Section 2. Quorum. At all meetings of the Health Review Committee, a quorum for the transaction of business shall consist of a majority of the entire Committee, and each member present in person or by telephone shall be counted toward the quorum. An act of a majority of the members of the Committee present at a meeting having a quorum shall be an act of the Committee. If at any meeting of the Health Review Committee less than a quorum is present, the Chairman may adjourn the meeting from time to time; and any business that might have been transacted at the meeting as originally called may be transacted without further notice at the reconvened meeting, a quorum being present.

Section 3. Meetings by Conference Call. Any meeting of the Health Review Committee may be held by conference call.

Section 4. Unanimous Consent. Unless otherwise restricted by the Articles of Incorporation or these by-laws, any action required or permitted to be taken at any meeting of the Health Review Committee may be taken without a meeting if all the

members of the Committee consent thereto in writing and the writing or writings are filed with the minutes of the proceedings of the Committee.

Section 5. Minutes Minutes shall be taken at all meetings of the Health Review Committee, and the outcome of all votes taken at such meetings shall be recorded in the minutes.

ARTICLE 10

OFFICERS AND OTHER EMPLOYEES

Section 1. Number. The officers of the Institute shall be the Executive Director (who, for purposes of the District of Columbia Nonprofit Corporation Act, shall be the "president"), the Secretary, the Treasurer, and any other such officers as the Board of Directors may, in its opinion, from time to time consider desirable for the conduct of the business of the Institute.

Section 2. Selection and Term of Office. The officers shall be selected by the Board of Directors and shall hold office, at the pleasure of the Board of Directors, until successors have been selected and have taken office. Any agent or employee of the Institute not selected by the Board of Directors shall hold his or her position of agency or employment at the discretion of the officer appointing him or her.

Section 3. Vacancies. Any vacancy among the officers of the Institute through death, resignation or other cause shall be filled by a person selected by the Board of Directors. The Chairman of the Board of Directors may designate an interim successor to fill a vacancy until a successor selected by the Board of Directors takes office.

Section 4. Removal. Any officer of the Institute may be removed at any time by the Board of Directors whenever, in the judgment of the Board, the best interests of the Institute would be served thereby; and any such decision by the Board of Directors shall be final and conclusive.

Section 5. Prevention of Conflict-of-Interest. No person may serve as an officer of the Institute who is employed by or otherwise regularly receives compensation from any governmental agency whose primary responsibility is protection of the environment or the regulation of motor vehicles, or who is an officer, director, agent, or employee of, or otherwise regularly receives compensation from, any corporation or other entity that manufactures, assembles, or distributes automobiles, trucks or other motor vehicles or engines for motor vehicles.

Section 6. Functions of the Executive Director. The Executive Director shall manage the day-to day affairs of the Institute in accordance with the orders, resolutions and policies

of the Board of Directors; shall execute all contracts authorized by the Board of Directors or the Health Research Committee; shall provide such staff assistance as may be needed by the Health Research Committee and the Health Review Committee; shall have general supervision and discretion of all the other employees of the Institute (except the members of the Board of Directors, the Health Research Committee, or the Health Review Committee) and shall see that their duties are properly performed; and, from time to time, shall report to the Board of Directors all matters within his or her knowledge that, in the interests of the Institute, should be brought to the attention of the Board of Directors. Subject to such exceptions as may be made by the Board of Directors, the Executive Director shall perform such functions as are customarily performed by the President of a corporation. He or she may appoint all agents and employees not required to be selected by the Board of Directors. He or she may sign, execute, and deliver in the name of the Institute contracts, bonds, and other obligations.

Section 7. Functions of the Secretary. The Secretary shall assist the Executive Director in administering the Institute; shall attend all meetings of the Board of Directors, the Health Research Committee, and the Health Review Committee and shall record and maintain the minutes and all votes at such meetings; shall give, or cause to be given, proper notice of all meetings of the Board of Directors, the Health Research Committee, or the Health Review Committee; shall keep the corporate seal of the

Institute and, when authorized by the Board of Directors, shall affix the seal to any instrument requiring the seal (and the seal, when so affixed, shall be attested by the signature of the Secretary).

Section 9. Functions of the Treasurer. The Treasurer shall assist the Executive Director in administering the Institute; shall have custody of the Institute's funds, securities and books of account and shall keep full and accurate accounts of receipts and disbursements in books belonging to the Institute, which books shall be open to inspection by any Director of the Institute and by the Executive Director; shall deposit all monies and other valuable effects in the name and to the credit of the Institute in such depositories as may be designated by the Board of Directors from time to time; shall disburse the funds of the Institute in accordance with directions from the Board of Directors and shall take proper vouchers for such disbursements, and shall render to the Executive Director and to the Board of Directors at each regular meeting of the Board of Directors, or whenever the Executive Director or the Board of Directors may require it, an account of all his or her financial transactions on behalf of the Institute and of the financial condition of the Institute; and shall perform such other duties as the Board of Directors may from time to time assign to him or her.

Section 9. Bond for Treasurer. The Board of Directors may direct the Treasurer to give the Institute a bond in a sum and

with a surety or sureties satisfactory to the Board for the faithful performance of the duties of his or her office and for the restoration to the Institute, in case of his or her death, resignation, retirement, or removal from office or disability, of all books, papers, vouchers, money, and other property, of whatsoever kind, in his or her possession or under his or her control belonging to the Institute.

ARTICLE 11

REGISTERED AGENT

The Board of Directors shall designate a registered agent of the Institute in compliance with Section 29-1009 of the District of Columbia Nonprofit Corporation Act.

ARTICLE 12

RESIGNATION

Any member of the Board of Directors, the Health Research Committee, or the Health Review Committee and any officer of the Institute selected by the Board of Directors may resign at any time. Such resignation shall be made in writing and shall take effect at the time specified in the resignation document. If no time is specified, the resignation shall take effect upon receipt

by the Executive Director or the Secretary of the resignation document. The acceptance of a resignation shall not be necessary to make it effective.

ARTICLE 13

CORPORATE SEAL

There shall be a corporate seal, which shall consist of the letters H, E, and I. The seal, an impression of which is affixed hereto, may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced, or otherwise.

ARTICLE 14

TRADE SECRET AND OTHER CONFIDENTIAL

COMMERCIAL INFORMATION

Section 1. Nondisclosure. The Institute, its Directors, officers, employees, agents, consultants, accountants, and counsel, shall not disclose to any person, except as provided in this article, any trade secret or other confidential commercial information (collectively, "Confidential Information") it has received. Except as provided in this article, this section shall apply to any data, information, or other materials (collectively, "Information") designated as trade secret or confidential

commercial information by any person or entity submitting such Information to the Institute.

Section 2. Exceptions. Section 1 does not apply to (a) Information developed in connection with studies supported or conducted by the Institute and disclosed in a form such that Confidential Information of a submitter cannot be identified, or to (b) Information required to be produced pursuant to legal process or official order. Information designated as Confidential Information but expressly permitted by the submitter thereof to be disclosed may be disclosed in accordance with such permission.

Section 3. Notice to Claimant. Whenever the Institute is notified that disclosure of Confidential Information subject to section 1 will be sought through legal process or is served with legal process seeking such materials, the Secretary shall immediately notify all persons and entities whom counsel to the Institute has reason to believe may claim an interest in resisting such process on the ground that the materials sought are Confidential Information. To the extent possible and legally permissible, the Institute shall take no action that would impair the ability of such a claimant to obtain judicial protection of its interest in the Confidential Information.

Section 4. Request from EPA. Whenever the Environmental Protection Agency officially requests Information designated by a

submitter as Confidential Information, the Institute may inform EPA of only the identity of the submitter.

ARTICLE 15

ADDITIONAL STUDIES

Any person or entity may request that the Institute conduct, or arrange through grants or contracts for the conduct of, additional studies that are not included in the Institute's research program but that relate to the health effects of motor vehicle emissions. The Health Research Committee shall review any such request and shall recommend to the Board of Directors whether or not the Institute should agree to the request. The final decision on whether to agree to such a request shall lie within the sole discretion of the Board. No such request shall be agreed to if it is not accompanied by an offer to pay for the full costs to the Institute of conducting or arranging for the studies proposed in the request, or if, in the judgment of the Board, the studies proposed in the request would constitute adversarial research or would otherwise be contrary to the purposes of the Institute. If a request is agreed to, any studies carried out pursuant to it shall be subject to the full control of the Institute and to the procedures of the Health Research Committee and the Health Review Committee as if the studies were part of the Institute's research program.

ARTICLE 16

NOTICE

Any notice required by these by-laws shall be considered to be given if it is mailed first class, postage pre-paid, to the address set forth in the records of the Institute.

ARTICLE L7

FISCAL YEAR

The fiscal year of the Institute shall be from July 1 through June 30.

ARTICLE 18

CHECKS AND NOTES

All checks and notes of the Institute shall be signed by such officer or officers or Director or Directors as the Board of Directors shall from time to time designate.

ARTICLE 19

ANNUAL AUDIT

The Board of Directors shall arrange for an annual audit of the financial books and records of the Institute by independent outside accountants. The accountants' report shall be available to any member of the public on request.

ARTICLE 20

ANNUAL REPORT TO THE PUBLIC

The Board of Directors shall issue, on behalf of the Institute, an annual report to the public, which shall report on the activities and condition of the Institute.

ARTICLE 21

COMPENSATION FOR SERVICES

The Board of Directors may authorize in its sole discretion the payment of reasonable compensation for services rendered to the Institute by its Directors, officers, employees, agents, consultants, members of the Health Research Committee, members of the Health Review Committee, accountants, and counsel, as well as

reasonable reimbursement for expenses incurred, by them on behalf of the Institute.

ARTICLE 22

INDEMNIFICATION

Section 1. The Institute shall indemnify any Director or officer or former Director or officer of the Institute, or any member or former member of the Health Research Committee or the Health Review Committee, or any person who may have served at the Institute's request as a Director or officer of another corporation, whether for profit or not for profit, or the heirs, executors, or administrators of any such Director, officer, or member against expenses actually and necessarily incurred by him or her or them in connection with the defense of any action, suit, or proceeding in which he or she is made a party by reason of being or having been (or being or having been the heir, executor, or administrator of) such Director or officer or member, except in relation to such matters as to which he or she shall be adjudged in such action, suit or proceeding to be liable for negligence or misconduct in the performance of a duty. Such indemnification shall not be deemed exclusive of any other rights to which such Director, officer or member or the heirs, executors, or administrators of any such Director, officer, or member may be entitled, under any by-law, agreement, vote of the Board of Directors, or otherwise.

Section 2. In the event of a settlement of an action, suit, or proceeding in which a Director or officer or former Director or officer of the Institute, or a member or former member of the Health Research Committee or the Health Review Committee, or any person who may have served at the Institute's request as a Director or officer of another corporation, whether for profit or not for profit, or any heir, executor, or administrator of any such Director, officer or member, is made a party by reason of being or having been such Director, officer, or member, or the heir, executor, or administrator of any such Director, officer or member, indemnification shall be provided only in connection with such matters covered by the settlement as to which the Institute is advised by its counsel that the person to be indemnified (or with respect to whom indemnification is to be paid to heirs, executors, or administrators) did not commit a breach of duty.

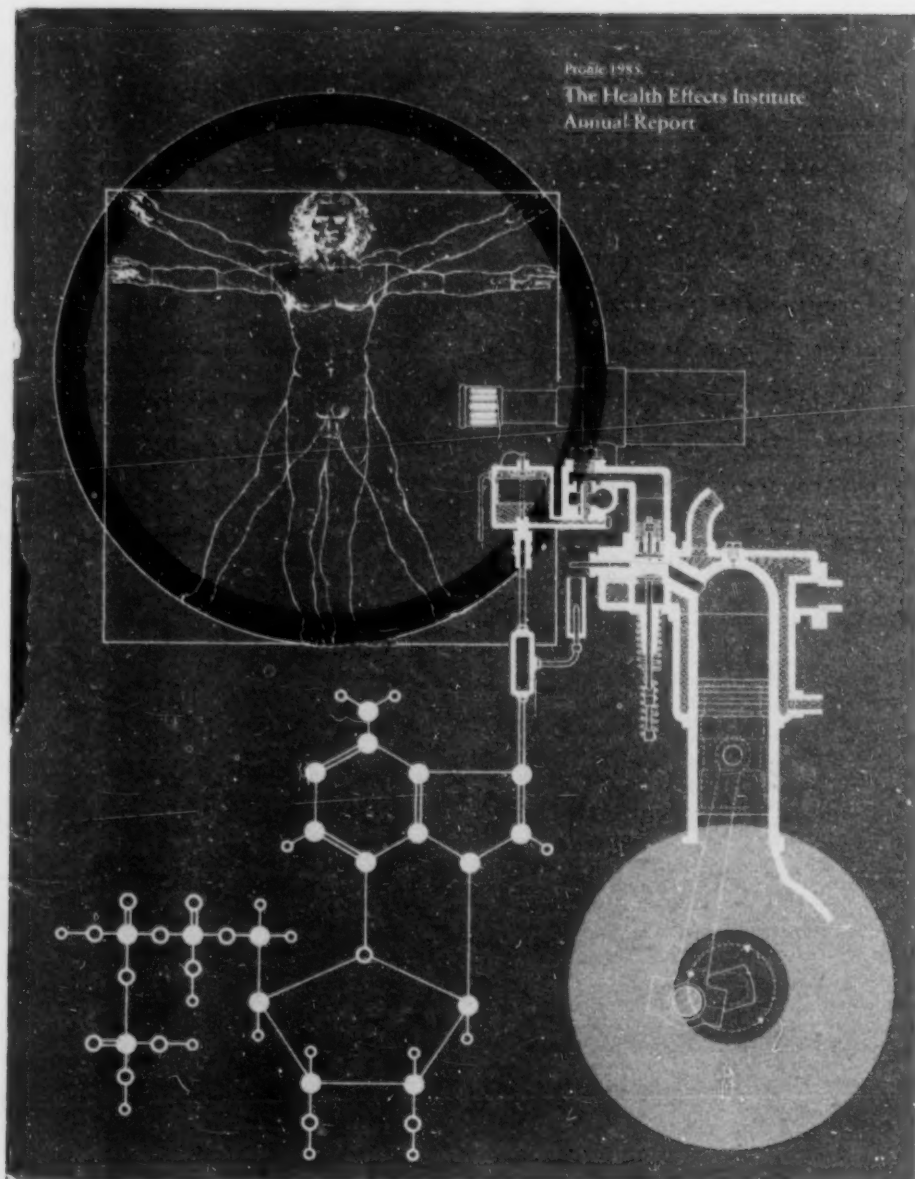
ARTICLE 23

AMENDMENTS

The Board of Directors may, by majority vote, amend or repeal any provision of these by-laws or of the Articles of Incorporation, except that the Board may not adopt, except with the approval of the Administrator of the Environmental Protection Agency and a majority of the members of the motor vehicle industry who contribute funds to the Institute, any amendment that (a) would amend or repeal or be inconsistent with the

statement of purposes set forth in Article III of the Articles of Incorporation or (b) cause the Institute not to comply with the requirement of the Federal Internal Revenue Code, as amended from time to time, for treatment as a tax-exempt organization, or (c) compromise the requirement of Article IV, Section 1, Article VI, Section 1, and Article VIII, Section 1 that members of the Board of Directors, members of the Health Research Committee, and Members of the Health Review Committee be objective in their views toward the health effects of motor vehicle emissions.

Profile 1983.

The Health Effects Institute
Annual Report

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Portrait: Charles W. Powers

The Health Effects Institute at a glance

Cover

Collage by Peter W. Johnson. Study of human figure by Leonardo da Vinci. Adenosine triphosphate (ATP) molecule. Schematic of Daimler engine, from Sigvard Strandh, 1979, *A History of the Machine*, A.B. Nordbok (Sweden), p. 145; reprinted by permission of the publisher.

Foreword from the Board of Directors
by Archibald Cox, Chairman



Archibald Cox
 Chairman



William O. Baker



Donald Kennedy



Charles W. Powers

Public debate about health and safety regulation has often involved bitter disputes about the quality of the scientific data and conclusions at its base. The search for scientific truth concerning the health effects of potentially harmful substances has far too often become a battle of pre-committed experts in which each side attempts to contradict the science of the other. The process subverts the purposes of science, debases the scientists themselves, and obscures real social policy differences that ought to be thoroughly debated. Furthermore, the lack of civility between the public and private sectors, and the substantial waste of resources involved in such conflicts between major industrial companies and the government is cause for real concern.

Consequently, I was greatly interested when invited by then EPA Administrator Douglas Costle and encouraged by William Ruckelshaus, while he was in the private sector, to chair a new organization, the Health Effects Institute (HEI), dedicated to quality science in regulation and to building bridges between the public and private sectors. We thought it essential, however, that this new institution be built in such a way that it would be truly independent and thus credible and accountable to the public. Three specific assurances were required:

- HEI must be independent in governance: The Board of Directors must be free to make its own choices based upon facts, after consulting the sponsors and other informed persons, and not be narrowly beholden for its decisions.
- HEI must have two-sector financial support: In order to secure its independent status, HEI must have the kind of financing that ensures both government and industry have an equal stake in the outcome of research.
- HEI must be dedicated to quality science from definition to review: The new institution must be structured to define, select, support, and review research to promote the application of the best science to the possible effects of mobile source emissions.

Senior management in both government and industry took the challenges seriously and gave the assurances. I became chairman of the Board of Directors; the other directors were Donald Kennedy and William Baker. Funding is provided on a fifty-fifty basis by the Environmental Protection Agency (EPA) and all twenty-four manufacturers of cars, trucks, and engines who market in the U.S. The manufacturers and the EPA under successive administrators have committed themselves to the hope that they can rely upon HEI as "the major source of studies on the health effects of motor vehicle emissions in the country."

For planning its research program and reporting the findings, HEI has developed a model process to ensure that, while independent, it is responsive to the needs of its sponsors and produces the highest quality work possible. It is a process to which the other members of the Board and I have devoted considerable time and effort.

In fiscal year 1985, HEI attained fully-funded operational strength for the first time since its inception in 1980. This report, HEI's first, is a profile of our first years of work, including the traditional financial tables, achievement summaries, and greetings from the officers.

But while the formal report serves a purpose, we think it also important to put HEI in perspective – to bring HEI, with all its complex issues and people, to life. To do that, we have chosen one study – the Multi-center Carbon Monoxide Study – as a case study, a vehicle through which we can explore the forces and illumine the personalities that infuse HEI.

We hope this documentary will convey some sense of the conviction and enthusiasm that those of us who are closest to the Institute feel. I know I speak for all the members of the Board in pledging our continued personal commitment to making HEI successful in the years to come, not only for the value of the particular enterprise, but as an example of what could be done by cooperation among government, industry, and the public interest community.

Health Effects Institute Board of Directors

- **Archibald Cox, Chairman**
Carl M. Loeb University Professor (Emeritus), Harvard Law School; Chairman, Common Cause. Formerly Solicitor General of the United States and Watergate special prosecutor. Harvard University LL.B., 1937, LL.D. (honorary) 1975.
- **Donald Kennedy**
President, Stanford University. Formerly Commissioner of the Food and Drug Administration. Harvard University Ph.D. (biology) 1956.
- **William O. Baker**
Chairman Emeritus, Bell Laboratories; Chairman of the Board, Rockefeller University, Princeton University Ph.D. (physical chemistry, polymer science) 1938.
- **Charles W. Powers**
President, Clean Sites, Inc. Founding Executive Director, HEI. Formerly Vice-President, Cummins Engine Company; Professor of Ethics, Yale University. Yale University Ph.D., 1969.

N.B. Just as Profile 1985 went to press, Charles W. Powers, HEI's Executive Director, became a member of the Board. Thomas P. Grumbly, who had been Acting Executive Director while Powers was on leave, has been named Executive Director and Treasurer. In the pages that follow, however, both are portrayed in terms of their prior roles.

Introduction

A brief history of the Health Effects Institute

Douglas M. Costle, Administrator
Environmental Protection Agency
December 12, 1980, press conference

1980 . . . Our understanding of atmospheric chemistry and the subtlety of these problems is still very fragmentary. Nonetheless, the Congress has passed statutes which require us to take regulatory action, usually under stricture of specific timetables. And we often have to act on the basis of what knowledge we have.

In the area of health effects, the fragmentary nature of what we know is even more acute. What we've been searching for is a mechanism by which we can efficiently coordinate the use of both private and public resources to fill in that data base. There is much we don't know that we need to do research on. Our concern has been that we not be going off in a hundred directions at once, that there [not] be unnecessary duplications of scientific research, and that we somehow avoid...doing defensive research.... Because of the nature of rulemaking and administrative law, we are often put in an adversarial setting. But when it comes to scientific data, we really ought to try to start with—as Hank Sebacht [of the Cummins Engine Company] put it to me three years ago—“a friendly set of facts.”

William D. Ruckelshaus, Administrator
Environmental Protection Agency
November 14, 1984, World Industry Conference
on Environmental Management

1984 . . . We are beginning to see the emergence of “bridging institutions” between industry and government and even between industry and the green machine (environmentalists). The old hostilities are breaking down, and old grievances are giving way to a spirit of cooperation, a new willingness to listen.

The Health Effects Institute is a perfect example of this potential. HEI is a cooperative effort paid for jointly by EPA and the automobile industry to evaluate the medical consequences of car and truck exhaust gases. Our goal is simply to gain acceptance by all parties of the data that may be necessary for future regulations.

It is impossible to understand what HEI is without understanding how it came into being. The passage of the Clean Air Act in 1970 gave the U.S. Environmental Protection Agency (EPA) the authority to set standards for car and truck emissions that would "allow an adequate margin of safety to protect the public health." That broad charter required the EPA to set standards for carbon monoxide, nitrogen oxides, ozone, sulphur dioxide and particulates emitted from cars, trucks, and buses; but the standard-setting process was fraught with difficulties.

Implementing the Clean Air Act standards was, according to Costle, "one of the most fractious environmental debates" of the 1970's. By 1980, there had already been ten years of confrontation between the EPA and the automotive industry over emission controls, and both sides were also confronting a new pair of requirements (sections 202(a)(4) and 206(a)(3)(b)) imposed by the 1977 Clean Air Act amendments.

Neither the industry nor the EPA were sure how to deal with those two sections. They stated that "...after model year 1978, no emission control device shall be used in a new motor vehicle or new motor vehicle engine which...will cause or contribute to an unreasonable risk to public health, welfare, or safety." Furthermore, the Administrator of the EPA was given authority to "test emissions and to require manufacturers to conduct such tests."

There was trepidation at this open-ended scientific challenge on both sides of the regulatory fence.

Both we and the government found ourselves in the position where the Congress had written into the law the requirement that, in the absence of something like HEI, was virtually impossible to comply with.... It was impossible, from the manufacturers' standpoint, for two reasons. One, we've always believed that the determination of what risk we as a society are willing to accept is not a determination that a private party can make, it's

a societal one...yet we had a law on the books that would have imposed that requirement on us. Two, there is the very practical issue that...the level of risk - setting aside the question of whether that level is acceptable - is a function of ambient loading [of pollutants], and [a single manufacturer is] not the only source of those.

From the government's standpoint, I think the requirements were unmanageable because, under the general principles of administrative law, regulated parties are entitled to know what is expected of them...so the Agency [EPA] was faced with having to specify for us the detailed requirements that we needed to comply with, such as how many constituents you test for, and how you test for them.

Helen O. Petruskas, Vice-President
Environmental and Safety Engineering
Ford Motor Company

Because the underlying research base to specify levels at which particular pollutants were not dangerous did not exist, the Clean Air Act in effect mandated new scientific methods and bold research programs. But the resources required to develop such programs or interpret their results were beyond the means of any single government or industrial institution - both in terms of costs and availability of appropriate first-rate scientists - and required cooperation in defining research.

"HEI was born out of necessity," says Ford's Helen Petruskas. Her sentiments were echoed by EPA's Stanley Blacker, director of quality assurance management, who wanted to "get beyond the issue of whether the health research results were or were not quality results....we wanted to set up some kind of organization where the results from the initial study, the health effects, would not be disputed; the interpretation of the results would be up to the involved parties - the regulator and the regulated - but the underlying data base we wouldn't be disputing."

A friendly set of facts was desperately needed. But if the need was clear, the way to meet it was not. It remained for one man - Charles Powers - to find the way.



To ignore the exceptional influence of this one man would be to miss a major part of [HEI's] story. While many people contributed along the way, and sometimes in a critical fashion, there would be no Health Effects Institute without Charles W. Powers. From concept, to founding, to implementation, Powers drove the process.

Thomas P. Grumbly, Acting Executive Director
Health Effects Institute
*In "The Health Effects Institute and the Future of
Regulatory Science"*

Powers started working on the concept of HEI in 1978, as an almost accidental outgrowth of his involvement, while an executive at the Cummins Engine Company, in the legislative process surrounding the 1977 amendments to the Clean Air Act. In 1980, after surmounting such major obstacles as funding and scientific process, he almost abandoned the project because of his inability to devise an acceptable governance mechanism. The breakthrough came about two miles outside the Baltimore-Washington International Airport, while he was driving collaborator Mike Walsh, then at the EPA, to catch a flight.

We got the idea to have a Board of Directors with three people that everyone respects. I think that was the breakthrough moment in HEI's life. The notion of having more than just a chairperson – a whole board – function in that way was unheard of, unprecedented. The idea of making independence inherent – you could never have any constituency directing Archibald Cox, Bill Baker, and Don Kennedy [HEI's directors] to do anything – that was right. But it took us a very long time to figure it out.

So we had this idea – but we didn't think there could be more than three statesmen in the whole country who would have those characteristics. Everyone said, "That's exactly the right way to do it, but you'll never find three people of any stature who will do it."

Charles W. Powers, founding Executive Director
Health Effects Institute

Powers persisted and compiled a list containing several hundred names of the requisite stature. He eventually winnowed it down to the right team of three, three who would do it, gladly – each member of the current board accepted the job without a moment's hesitation.

The Articles of Incorporation for a non-profit corporation "organized and operated...to support the conduct of, and to evaluate, research and testing related to the health effects of emissions from motor vehicles" were signed in May 1980. HEI's establishment was formally announced at a press conference in December of that year. The hopes and dreams that abounded then were captured most succinctly by the words of one of the new board members:

We now have a framework within which the scientific data that supply the basis for public policymaking will be produced under the best scientific auspices, and thus in a way that, so far as possible, will assure their credibility to EPA, the industry, public interest groups, the Congress and – most important – the public. As long as scientific research on the health effects of motor vehicle emissions is needed, I expect the Institute will provide it in an authoritative way – without regard to political philosophy or viewpoint on policy issues.

Donald Kennedy, Director
Health Effects Institute

With Powers at the helm as Executive Director, the Institute sprang into action. But the early years of any new institution are ones of testing and coalescing; the careful planning that preceded HEI's launch gave the fledgling organization a head start, but could not catapult it directly into adolescence. The first tests were passed when top-notch scientists were drawn to HEI's standing committees, the Research Committee and the Review Committee. Although their commitments were encouraging, it was always clear that these outstanding scientists would remain with HEI only as long as the independence of the Institution was vouchsafed.

That inevitable watershed also came in the early years, culminating, according to several accounts,



when members of HEI's Board and Research Committee walked out of a meeting with government and industry sponsors rather than submit their research agenda to outside review. After that, the drama was more low-keyed, centered on exploring, understanding, and charting the gaps in the existing data base of environmental science. The Research Committee, chaired by Walter Rosenblith, led this effort. By the spring of 1982, the first set of Requests for Applications was issued, followed by the second set a year later. The first contracts were actually let in the spring of 1983, and in the summer of 1985, the first final report – on a small, well-defined project – was released to the sponsors. By the middle of 1985, all of HEI's organizational engines were operating at full strength.

Now HEI is old enough and established enough that the questions are focused, appropriately, less on the Institution's survival and more on its performance, on the emerging science that is its *raison d'être*. In a recent letter in which the EPA administrator reaffirmed the agency's intention to continue funding HEI, he also commented that:

HEI has completed its start-up phase and is now entering another critical stage. Results from relevant health effects studies will become available over the next several months for use by the EPA. Issues of relevance, timeliness, and quality will be analyzed by all interested parties. EPA expects during this stage to document that HEI-funded study results are important to the decision-making process. . . . HEI has established an excellent review process under the leadership of Dr. Robert Levy.

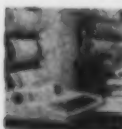
Lee M. Thomas, Administrator
Environmental Protection Agency

As Administrator Thomas notes, the review process began full-scale operation only recently, although the Review Committee has been preparing for its work for over a year. This seeming delay simply reflects time lag, the gap between money going in and science coming out. This year – fiscal 1985 – marks the first year that any experimental results have emerged from the HEI process. Hence

it is the first time the Health Review Committee – the last of HEI's organizational components to become fully operational – has been called into action.

During the course of the next year, many more studies will come to fruition, including some that represent major commitments on the part of HEI. A special section – "Perspective" – is devoted to one of them, the multi-center study on the acute effects of carbon monoxide exposure on subjects with angina pectoris. Although this study is not entirely representative of HEI's research agenda, it has nevertheless been singled out for attention. Why? Partly because it reflects a mode of operation in which quality science and near-term relevance are merged. Partly because of its sheer size – HEI will spend more than \$1 million in 1985 and 1986 to complete and evaluate this set of studies, making it the largest single experiment underway. Partly because it represents an immediate application of quality science to a real-world standard-setting issue – as one knowledgeable observer put it, "...results of the CO multi-center study will strongly influence, if not determine outright, the next setting of the National Ambient Air Quality Standard for carbon monoxide." And partly because its intricacy makes it a wonderful vehicle for illustrating vividly – instead of merely documenting – how HEI works and how quality science is done.

We hope that, in reading "Perspective", as well as the rest of *Profile 1985*, you will get a sense of the spirit of this place, the problems and possibilities involved in doing quality environmental science, and something of our hopes for this kind of science in the future.





The CO exposure chamber: see page 15.

Perspective

An HEI Case Study *The Multi-center Carbon Monoxide Study*

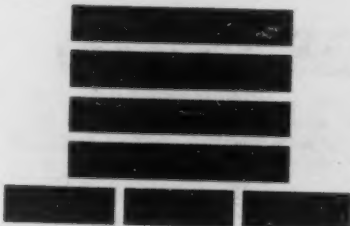
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An HEI case study

The Multi-center Carbon Monoxide Study

Somewhere between the formalism of charters and the jargon of science lies reality: real people faced with real projects and practical problems. The pioneering significance of the HEI charter is not diminished by the observation that HEI's real strength is in its people—scientists, sponsors, staff—and their intelligence, dedication, concern, commitment, and simple humanity. As HEI has moved from an idealistic concept to an institution that works, it has established research projects and scientific teams that can translate abstract concepts into mission-fulfilling reality.

Dynamics of the Multi-center Study
Main channels of communications among participants while study is in progress.



There seemed no better way of illustrating how these unique people transform principles into action than through a case study. And there seemed no better project for a case study than the Multi-center Carbon Monoxide (CO) Study. HEI will spend over \$1 million to complete this set of studies, making it the largest single experiment underway. Moreover, the way in which this study is managed and carried out will significantly influence the future of the Institute.

Recognize, though, that the CO study is not really a "typical" HEI study. Aside from its sheer size, it is also distinguished by its focus on a straightforward regulatory objective, a solution for an immediate problem; whereas most of HEI's research projects focus on longer-range objectives aimed at some deeper understanding of the health effects of mobile source emissions. But the multi-center study's inherent administrative complexity serves, with a single cohesive example, to illuminate almost all the workings of HEI, including aspects of HEI's interaction with sponsors, administrative functions, and use of superb scientists to guide the research and review processes. It also illuminates the obstacles in the path of quality science, difficulties that on some scale are typical of all HEI studies. And finally, it will illustrate that the differences—sometimes consonant and sometimes dissonant—among HEI's people in perspective, training, responsibility, accountability, personality, and circumstance are essential to the Institute's intellectual vitality.

The size, scope, complexity, and controversy of the CO study provides much drama and makes for good reading. What follows is in no sense intended to be a scholarly presentation of

the work in progress, but rather a series of different perspectives on both HEI and the science of CO, provided by a combination of narrative, interview, and photographs, that will bring both individuals and issues to life. Prevailing opinion about this study is divided: will it be definitive or won't it? But whatever cautious opinions on these matters are ventured—and scientists are appropriately cautious about anticipating experimental outcomes—there is surprising unanimity about the intrinsic value of any study conducted as painstakingly as this one.

HEI's own position reflects these views. HEI holds that the completeness of this process is critical to the credibility of the ultimate scientific and policy outcomes in the area of mobile source research. Taken together with HEI's overall research program on CO, these studies will create a firm basis for assessing the health effects of low concentrations of this pollutant. HEI is investing a substantial sum in public and private funds to resolve a question that has nagged scientists and regulators for the past decade. The benefits of this investment in impeccable process and quality science are increased public confidence in both government and industry.

Stating the problem: EPA's request to HEI

The problem...was that, whenever EPA proposed a regulation, there would be public hearings and then...we never could get beyond the issue of whether the health research results were or were not quality results.

Stanley Blacker
Environmental Protection Agency



Stanley Blacker

Stan Blacker, in his densely packed office at the EPA's headquarters in southwest Washington, is the director of the Quality Assurance Management staff. He is also the EPA's liaison for HEI matters, and is a living archive of HEI history, having been heavily involved with HEI even prior to its inception. At the time he spoke the words above, he was referring generally to the problems leading to that inception. But he could just as well have been describing the uneasy history of the carbon monoxide National Ambient Air Quality Standard (NAAQS).

Perspective

About 85% of the carbon monoxide (CO) in the urban atmosphere is due to mobile sources. The EPA is responsible, under the provisions of the Clean Air Act, for establishing NAAQS that protect the health of the most susceptible groups. Each standard is subject to review and revision every five years.

The original CO standard – an average of nine ppm over eight hours and 35 ppm for one hour – was based primarily upon neurological effects. Exposures at these levels had yielded carboxyhemoglobin levels between two and three percent in humans, with demonstrable neurologic effects. But later, investigators were unable to reproduce the original results, and instead showed that neurologic effects do not occur at carboxyhemoglobin levels below five percent.

At the same time, new work was reported with cardiovascular effects, using as an indicator what some researchers consider the most sensitive measure of the acute effects of CO exposure in humans: the length of time a subject can exercise before the onset of pain arising from angina pectoris or vascular disease. Specifically, the new results reported a decrease in this indicator at levels of carboxyhemoglobin as low as two percent.

In 1980, the recent cardiovascular data led EPA to propose a revision of the carbon monoxide NAAQS. The new standard would be lowered to 25 ppm for one hour, a recommendation supported almost exclusively by the cardiovascular data; the neurologic data had been rendered irrelevant.

However, the cardiovascular studies themselves were soon called into question. An excerpt from an independent scientific appraisal of one study in particular summarized the EPA's predicament: "...Even if no inconsistencies were present in this study, it would be rash to rely entirely upon one study with ten subjects....It would be equally irresponsible to disregard these findings."

This impasse eventually led Courtney Riordan, then Acting Assistant Administrator for Research and Development at the EPA, to write to HEI in July 1983:

EPA needs to determine whether Dr. Aronow's observations, an important part of the basis for the 1980 revisions to the national ambient CO standards, can be duplicated. EPA, state and local agencies, and the regulated community would like to obtain additional health effects data to clarify whether effects can be observed in the range of 2-4% carboxyhemoglobin....We need a study similar to that performed by Dr. Aronow which measured the decrease in time to onset of angina as a result of CO exposure. His medical patients were medically stable, were exposed to [ambient] CO levels resulting in [blood] levels of 2-4% carboxyhemoglobin, and were exercising during the experiment.

Defining the research: How HEI initiates research projects

Because the Health Effects Institute (HEI) was established to perform quality health effects research on motor vehicle pollutants concerns (e.g., CO), we would like HEI to consider sponsoring this independent study. In a recent Request for Applications, HEI recognized the need to do research on the health effects of CO.

Courtney Riordan
Environmental Protection Agency

As Riordan acknowledged in his letter, the Health Research Committee, the distinguished group of scientists responsible for HEI's research activities, had just sent out a Request for Applications (RFA) in support of a carefully balanced carbon monoxide research program. Neither the timing nor the scope of that RFA surprised anyone familiar with the dedication, intelligence, and perceptiveness of Walter Rosenblith, the Committee's chairman, and his colleagues.

HEI Executive Director Charles Powers considers the Committee's respect for scientific balance one of HEI's greatest strengths. "The regulatory community gets focussed on one piece



Walter Rosenblith

of a possible problem, takes one kind of evidence as a basis for regulation, and rides everything on it....An organization like HEI, by consistently taking a broad look at the full range of physiological effects, and refusing to get boxed into any one parameter, I think has protected itself, and importantly, changed the way environmental science is being done." In the RFA in particular, Powers observes, the Research Committee "had made sure that it was *not* focussed only on angina pain; [it] was also looking at whether or not CO caused exacerbation of symptoms of people who had chronic obstructive pulmonary disease, whether or not it had increased the response of people who had sickle-cell anemia, whether or not people who are older, whose cardiovascular systems were older, had adverse response to CO."

Since Riordan had closed his letter by asking to know "in the next few weeks whether HEI will agree to perform this specific study," Powers promptly passed the letter on to Health Research Committee Chairman Walter Rosenblith. At HEI, such research decisions are made *only* by the Research Committee and the Board.

The EPA's needs were both specific and immediate, and responding to the request would therefore mean a departure from HEI's usual way of doing business (see "Research activities" for a fuller explanation of these procedures). Nevertheless, Rosenblith and his colleagues felt the legitimacy of those needs and quickly agreed to undertake a study.

But what study? The Health Research Committee felt strongly that the EPA request should be used to demonstrate how quality science with a near-term regulatory goal should be conducted. Accordingly, the Committee's immediate objective was to explore the scientific questions in a definitive and credible way, and in the shortest time necessary to conduct a first-class study. A dedicated team would be needed to guide this effort, so the Research Committee, in August 1983, established the CO Oversight Committee.

Defining the protocol: The CO Oversight Committee launches the Multi-center Study

Roger [McClellan] is incredible. He works seven days a week, about 15 hours a day. He calls me from airports all the time; he's in there Saturdays and Sundays doing all kinds of work. And he's up on everything; send him stuff from HEI and he looks at it and he writes....He's a very demanding person, not easy to work for, but he's not the sort who drives his staff and doesn't work hard himself. I'm sure he works harder than any of them.

Jane Warren
Health Effects Institute

Dr. McClellan explained the role of the CO Oversight Committee on a brilliantly sunny desert day at the Lovelace facility that he directs, just outside Albuquerque, New Mexico. McClellan could be the personification of the HEI "mystique"—he is a "bringer", whether of scientific disciplines or institutional sponsors, a person to whom the greatest good is making something whole out of disparate parts. McClellan functions in dual roles as an HEI participant, and at the same time as director of "one of the largest institutions in the world which directs its attention to the effects of airborne pollu-



Roger McClellan

stants." He spoke about the CO study and the Oversight Committee while we toured Lovelace.

"The Oversight Committee is a partnership between HEI and the group of investigators...it really is an operating arm of the Research Committee." As a bridge, McClellan is an articulate proponent of just such a partnership approach to the scientific problems of the twentieth century:

When you can back off a little bit, you get a different perspective in terms of what the problems are, in contrast to what you get pursuing a career in which your goal is to understand a single one of the various cell types in the respiratory tract...We need that, but we need also, somehow, to take the macrophage in the lung and put it into the perspective of the whole lung, and then into the perspective of the whole body, and then into the atmosphere that people are breathing. You do that by being involved with a group of people. You can't do those studies by yourself. The only way to get it done is to bring together a team of people.

The convening of the Oversight Committee itself, McClellan noted, demonstrated the kind of flexibility and strength that HEI can muster. The charter members of the CO Oversight Committee were:

John Tukey, Chairman
Princeton University, Bell Laboratories
Joseph Brain
Harvard School of Public Health
Roger McClellan
Lovelace Inhalation Toxicology Research Institute
Stephen Achuff
Johns Hopkins Hospital
Stephen Ayres
St. Louis University School of Medicine
Steven Horvath
Institute of Environmental Studies, University of California at Santa Barbara

Of these, three were members of the Health Research Committee (Tukey, McClellan, Brain), two were cardiologists (Achuff, Ayres), and one (Horvath) was an environmental physiologist who had been the author of the EPA's review of the Aronow study. Thus, the Research Committee was able, on very short notice, to create a small but expert task force, one that could credibly tackle CO's scientific challenge without becoming mired in red tape.



The multi-center study's principal investigators - the pulmonary physiologists - meet with members of the CO Oversight Committee and the Data Management Center at Harvard. Clockwise from left are: HEI's Raahid Sheikh, Tom Dahms, Gene Blescker, Joe Brain, Jack Hackney, and Harvard's Karen James.

Almost immediately, the Oversight Committee concluded that an adequate study should utilize identical protocols at more than one research center, to guarantee that results could be reasonably interpreted and that institutional biases would be eliminated. But that would mean that protocols proposed by individual investigators could not possibly be appropriate. Thus HEI, through its committees and staff, took a more active role in the design and planning of these CO studies than it did in other studies.

By August 1983, HEI had indicated to potential investigators that the EPA request necessitated a different application process. By September 1983, the Oversight Committee had developed a series of standard indicators and a study plan, and HEI sent that information - in a special mailing - to the heads of cardiology departments at 271 medical schools and hospitals, as well as to all recipients of previous HEI REAs in the area.

Applications from prospective investigators were received by October. Because the Oversight Committee decided to develop detailed protocols after the investigators were selected, the application review process primarily involved reviewing qualifications, facilities, and availability of subjects. An attempt was also made to screen out

investigators who may have had bias or preconceptions arising from prior involvement in the CO controversy.

In November, the Health Research Committee and the HEI Board of Directors approved the selection of the following investigators:

Eugene Blecker
Sidney Gottlieb
Baltimore City Hospital
The Johns Hopkins University School of Medicine
Bernard Chassin
Thomas Dahms
St. Louis University School of Medicine
Jack Hackney
Ronald Selvester
Rancho Los Amigos Hospital
Downey, California

The investigators, the Oversight Committee, and the HEI staff, with John Tukey leading the way, made the key decision not to attempt exact replication of the Aronow study, and, starting in late December, they began to develop a protocol. The two indicators of myocardial ischemia chosen for measurement were the length of time from the start of exercise to the onset of angina, and to the onset of depression of the ST segment of the electrocardiogram (a more objective endpoint than the pain of angina). Although additional objective measures were sought, those that were proposed were all considered to interfere with measurement of time to the onset of angina, so they were rejected.

An extraordinary quantity of minutiae in a protocol demand attention if first-rate science is to be achieved; in a multi-center study, where that first-rate science must be carried out in a consistent fashion at three different sites, that quantity is mind-boggling. Furthermore, it is not enough to resolve most of the fine points; one major flaw can mar the whole experiment. The Committee, despite occasional differences and minor tensions, worked through copious details but a few were maddeningly resistant to resolution.

"We have a brief controversy right now, in terms of some questions of how one measures

carboxyhemoglobins, and that has involved a lot of interaction between the Oversight Committee, the people at St. Louis, and the consultants at Stanford University," says McClellan. Of course, there is no quick cure for such resistant species. "The measurement controversy," he notes, "will be resolved in parallel with the completion of the study, not before."

Another pivotal point required a study in and of itself; this was the repeatability of individual uptake rates. In experiments of this kind, it is com-



Ron Selvester, left, cardiologist, and Gene Blecker each bring a different perspective to the CO study

mon practice to repeatedly use identical CO concentrations and exposure times at each experimental exposure; such, in fact, was the protocol in the Aronow study. But for the multi-center study, an alternative method was proposed, in order to keep "tight" control of the patient's exposure. This tight control would permit more powerful statistical comparisons. But achieving it called for the experimental subjects to be exposed to concentrations of CO that varied according to the individual's rate of uptake. Properly exposed, each subject would then reach an end-loading concen-



Tom Dahms, left, and Jack Hackney



Jane Warren

tration of carboxyhemoglobin close to some predetermined target level. Individual uptake rates could be determined at a preliminary testing session, but would be useful only if they did not vary from day to day. That kind of individual repeatability would be a reasonable expectation, but required experimental verification. Thus a pilot study was conducted at St. Louis University which did indeed confirm this hypothesis.

As we turned back to the main building at the end of the tour, Dr. McClellan observed, "I don't have any vested interest in terms of *what* the standard is, but cities need to know that any standard is scientifically defensible. They don't want numbers pulled out of the air." There are consequences to compliance, he points out, that often are not appreciated. "Federal funds can be withheld for non-compliance, not just air pollution funds, but sewage treatment and highway building funds." And there are still other implications: "Should my grandmother move? People at the bench often don't appreciate the ramifications of these decisions."

Coordinating the participants: The HEI staff orchestrates the Multi-center CO Study

You see, the HEI staff is, in a sense, the action arm of the Oversight Committee....arranging and coordinating the building blocks for the study in terms of the appropriate operating procedures, the appropriate protocols.

Roger McClellan
HEI Health Research Committee

The painstaking work of organizing a protocol, developing channels of communication among the investigators, coordinating quality assurance procedures and data analysis, devising standard operating procedures, and generally providing support, services, and understanding to anyone connected with the CO study fell mostly to Dr. Jane Warren, senior HEI staff scientist and project manager for the CO study. Anyone who underestimates either

the extent or complexity of that effort need only contemplate the dimensions of the Procedures Manual.

Jane Warren is quiet, soft-spoken, eminently capable. Nor is she a novice in the world of scientific research: she holds a Ph.D. from Princeton in genetics and developmental biology, and spent a number of years as a research fellow at Harvard, most recently at the Energy and Environmental Policy Center, before joining HEI in 1983.

But she found herself a novice when it came to designing this sort of protocol. What did she expect writing the protocol to be like? "I thought it would take a couple of days of discussion. I never dreamed it would get so complicated." The development of the final protocol, though, consumed the period from December 1983, when work began in earnest, through the final sign-off in March 1985. What happened in that interval?

The CO Oversight Committee realized, in February 1984, that a pilot study of uptake rates would be necessary. The pilot study could not begin until July, and was not completed until the following November. With the hypothesis underlying the experimental procedure confirmed, the rest of the time was spent developing and documenting the standard operating procedures. Note that the final protocol itself, including a historical overview and appended reference tables, is only 25 pages long. That protocol was formally signed by the investigators in March 1985, and the first patients seen in May.

Warren observes that it took a long time to set up this protocol, and that, even now, progress has been slower than had been hoped. She explains the delays clearly, summarizing in the abstract:

Different people exposed to the same levels of CO for the same time won't take in the same amount. So the effort has been to make the carboxyhemoglobin levels the same for each patient at the end of exposure, and that's pretty complicated....it's a really messy area, trying to hit the CO level exactly. Much of the delay in the experiment has been caused by trying to reach these target levels, which in turn has made us dependent on the CO-oximeter to an extent that we wouldn't have been otherwise.

Performing the experiments: Putting patients on the exercise treadmill

The CO study is raising the level of science in the field. So even if the results are bo-hum, with that kind of rigor in the method, this study is ground-breaking. It will set a new standard.

Thomas Dahms
St. Louis University School of Medicine

Tom Dahms and Bernie Chaitman work well together. Chaitman is the cardiologist, Dahms the "pulmonary function man." Dr. Chaitman was supervising the first non-baseline exercise testing for the first patient – let's call him Mr. Jones – in the study. Chaitman explained carefully that he'd prefer that Mr. Jones not be observed until after the exposure and testing had been completed, saying that the presence of visitors might make him nervous, and perhaps change his endpoint, which depends on central nervous system factors, among other things. He smiled and said, "We've gone to such care to develop procedures to guarantee uniformity that to introduce an anxiety-provoking stimulus would – could – ruin the



Rashid Shalish ponders the substitution of carboxyhemoglobin measurement during a break at the July meeting of the CO Investigators. Rashid, a newcomer to the HSI staff, found himself acting Project Manager for the CO study this summer, while Jane Warren was on maternity leave.

Standard operating procedures

It is difficult to convey, without actually living through it, the full sense of the attention to detail that quality science demands. In a study involving several sites, such as this one, consistency in replicating those details becomes even more important, otherwise the resulting data may not be pooled for analysis. In order to give some sense of the degree of care invested, the table of contents of the Procedures Manual is reproduced below; this Manual is fully two inches thick.

whole experiment. Also," he added, deadpan, "we want Jones to show up for his next visit."

In the EKG-reading room, Dr. Dahms talks about the intricacies of carboxyhemoglobin measurement methodology while we wait for Mr. Jones to finish. The CO-oximeter was originally designed, he notes, by Instrumentation Laboratory, a Lexington, Massachusetts firm, for use in providing quick oxygen assays used in cardiac catheterization labs. It migrated to use for CO measurements on smoke inhalation and suicide victims, where the measurement levels are gross—the need is to distinguish between 5% and 50% carboxyhemoglobin levels. But environmental medicine calls for looking at carboxyhemoglobin levels—all well below 5%—in normal and compromised patients. Thus the problem, continues Dahms, arises when you try to apply this device—with its manufacturer-specified error of 1%—to distinguish small differences between such low levels of carboxyhemoglobin.

Dahms starts to speculate that lipids—say a breakfast of bacon and eggs—could skew the colorimetric analysis that's at the heart of the CO-oximeter. He's interrupted by Chaitman, who has come to tell us that the testing is finished for the day. But Mr. Jones, a stocky, open-faced, good-natured man, is very obliging about demonstrating the exposure chamber procedures for curious visitors.

Later, the measurements discussion is resumed in Dahms' lab across the street. The central question is whether CO-oximeter measurements are related to gas chromatography (GC) determinations of carboxyhemoglobin by a constant arithmetic offset. The experimental protocol has posited that they are, but so far, it has proved difficult to determine the value of that constant. The GC determinations are considered more reliable, but the equipment itself is more complex, costly, and less common in clinical labs. If Dahms is correct in hypothesizing that serum lipid levels may artificially elevate the CO-oximeter's determinations by increasing the blood sample's opacity, then the postulated constant would also depend on the subject's lipid levels.



Thomas Dahms



Bernard Chaitman

Dahms voices frustration over the measurement problem. He points out, as did Jane Warren, that the straightforward concepts underlying the whole study pivot about these measurements, which in turn are compounded by lack of understanding of the physiological mechanisms of uptake. "No one," he argues, "has succeeded in making sense—physiological sense—out of their data for ten or twenty years." By Dahms' reckoning, this experiment will be superficial because it does not attempt to understand "some basic issues in carbon monoxide that need to be dealt with, such as what determines the individual's rate of uptake."

In addition to his responsibilities as a principal investigator in the study, Dr. Dahms directs a reference laboratory for standardizing carboxyhemoglobin measurements at all three centers. All the investigators have worked with the CO Oversight Committee and the HEI staff to design the careful standardization protocols that are included in the Procedures Manual and monitored by Dahms. "It's usually a difficult thing in science to really validate your methods," says Dahms. "I'm getting bogged down in that, and that's not where the fun is, as far as I'm concerned; I'm more interested in the basic physiology."

His heavy involvement with equipment and methodology is ironic. Dahms originally wanted to be an engineer. He discarded that ambition when he realized he found the subject boring, and followed his interests into what he describes as "functional anatomy." Like Roger McClellan, Tom Dahms espouses the HEI philosophy, a "top-down" interest in systems—animal and societal. Or, as Dahms puts it, "There is a standing rift between people working with the system approaches versus cellular system approaches versus sub-cellular system approaches; what I see is that we are all needed, we are all interdependent. If you can't make what goes on at the cellular level make sense in the organ system approach, then there's something wrong with the cellular level, and likewise in the other direction."

Synopsis of experimental protocol

Selection of experimental subjects

The most indicators of myocardial ischemia in the coronary are changes in the rate of oxygen, and in the rate of ST segment depression in the electrocardiogram.

Subject selection

The subjects to be studied will be males between the ages of 35 and 70 who have not smoked for at least three weeks. Coronary disease, drug therapy, were chosen on the basis of the maximum range of oxygen. They are selected who are thought to be able to study, but must be expected to be able to show an effect of a given dose of oxygen, and for the required conditions. Each subject will receive stable, controlled oxygen therapy and must have a positive response to at least one of myocardial ischemia as defined by electrocardiogram depression with myocardial oxygenated oxygen.



One of the subjects in the laboratory. The use of the CD reference laboratory is required for the study. The "CD" reference laboratory is required for the study. The "CD" reference laboratory is required for the study. The "CD" reference laboratory is required for the study.



The patient room in the laboratory during a simulated procedure.

In addition, for each subject there must be evidence of at least one of three other indicators of ischemia: heart disease. These are: a negative history of at least 70 percent narrowing of at least one major coronary artery, prior myocardial infarction, or a positive thallium stress test. The subjects are selected for the study.

The first or baseline visit will consist of the following steps:

- History and physical examination
- Informed consent
- Baseline laboratory tests, including electrocardiogram
- Exercise treadmill test A
- Recovery period
- Baseline treadmill test B (precardiac catheterization)
- Recovery period
- Treadmill test C (postcardiac catheterization)

Exposure Protocol

After preliminary screening and selection at the baseline visit, subjects will undergo three test sessions on three separate days. On each day, the subject will be given an initial exercise test, exposed for one hour to room air or to air containing an elevated level of carbon monoxide, and then given a second exercise test. Elevated carbon monoxide exposure will occur at two different levels, one at 2% and one at 4%, as determined by gas chromatography methods. All subjects

will be exposed to chambers, rather than by masks, and their exposure will be performed on a treadmill. Neither the cardiologist nor the subject will know whether the air contains carbon monoxide or is pure air or is one of the elevated levels of carbon monoxide.

The experimental visits (the second, third, and fourth visits) will consist of the following steps:

- Exercise history and physical examination
- Laboratory test, including electrocardiogram
- Exercise treadmill test A
- Recovery period
- Double-blind exposure (30, 70 minutes) to high CO, low CO, or room air
- Exercise treadmill test B

Cardiothoracic Measurements

One of the three centers (Dr. Kohn) will perform cardiac catheterization studies for the others as well as calibrating the CO system. The CD reference laboratory will also obtain a fraction of the samples obtained at the other laboratories to ensure the validity and accuracy of measurements at each center. The importance of accurate measurements of carbon monoxide levels, as well as of CO exposure levels, is clear.



Baseline tests of subjects in the laboratory. The "CD" reference laboratory is required for the study. The "CD" reference laboratory is required for the study.

Monitoring the procedures: Quality assurance in the laboratories

The business of quality assurance is verifying that, in fact, you have the information that actually reflects the experiment.

Andrew Sivak
Arthur D. Little, Inc.



Andrew Sivak

All along, a stringent quality assurance plan has been considered part of the experimental protocol. The CO Oversight Committee expected quality assurance to be achieved by six basic means:

- Agreement on and use of written protocol;
- Use of written standard operating procedures that cover all relevant procedures and equipment and that are simple, complete, consistent with sound scientific priorities, and adequate to establish traceability of standards;
- Involvement of qualified personnel;
- Maintenance of adequate written records;
- Use of appropriate data-processing techniques;
- Use of quality assessment procedures, including assessment for precision, accuracy, representativeness, and comparability.

The quality assurance aspects of the study are being handled by Dr. Andrew Sivak, of Arthur D. Little (ADL), Inc. Denise Hayes is the quality assurance officer for the study. Dr. Sivak was originally trained as a biochemist and microbiologist whose early interests lay in cell biology and mechanisms of carcinogenesis. He started out as a senior staff biochemist at ADL in the early '60s, then spent 11 years at NYU's Institute of Environmental Medicine. He returned to ADL in 1975 and started moving more and more into toxicology.

ADL brings two main strengths to the CO study. First, scientific expertise: besides Sivak, the ADL staff offers scientists with experience in pulmonary physiology and in CO measurements in experimental systems. And second, quality assurance experience: ADL is a very "pro-active" quality assurance organization, since some of ADL's work for commercial clients gets submitted to regula-

tory agencies and must comply with Good Laboratory Practice standards.

In mid-1984, he was contacted by HEI's Tom Grumbly, who, says Sivak,

...indicated that they were interested in having somebody look at one of the studies they were doing from a quality assurance point of view; they even wanted a third party review. "Yes, we had quality assurance people here, we had people who understood what that meant, we had people who were biologists, pharmacologists, and physiologists, who could understand what the experiment was all about."

We came in after the first set of protocols was already on paper. Then we started working with HEI and the investigators to ensure that the protocol would fit in with an appropriate quality assurance protocol. We identified the critical phases that we, as quality assurance people, could go in and monitor. For example, we had to know what the concentration of carbon monoxide was in the exposure chamber, therefore the protocol that was written to deliver carbon monoxide to the chamber had to have in it appropriate measuring steps and appropriate recording steps. So that when we come back and look at the books on, say, an experiment done on July 22 in Baltimore, we know that the notebook accurately reflects what the concentration was.

Of course, Dr. Sivak hastens to note, there are limitations. "If we're looking at data that are developed by automated machines, for example an automatic CO sensor in the chamber, then the printout of that sensor becomes part of the laboratory notebook." On the other hand, suppose the



only way to obtain a measurement is for a laboratory technician to read a thermometer and transcribe that reading into a notebook. "It would be OK if that were the only way," he explains, but notes there are other ways still of authenticating the information. "We would say, 'Show me the validation of your thermometer; how do you know your thermometer is really reading that? How do we know the person that is recording is trained to do that; show me the training schedule of that person. Can we watch this person do that, to assure ourselves that he can do it?'"

And in fact now that the protocols are completed and the study underway, visiting and observing form the main component of the quality assurance program. "Either Denise or myself," says Dr. Sivak, "will visit each of the laboratories on days they are actually doing tests, so that we will verify that they are, in fact, doing steps 1 through 22 as they say they are. We have already been to each of the laboratories to make sure that their equipment, their protocol books, their training manuals, and all the people are there."

To get to that point, though, it was also necessary to build team trust and rapport, a task Sivak accorded number one priority:

When we first walked onto the scene with these three academic laboratories, of course, they were perturbed: "You're not bringing anybody in here to monitor us, we know what we're doing." So, from the beginning, we tried to tell them, "You know, we're not opponents, we're part of the team," and explained what we were trying to do. They all knew that, because of past history of this study, the quality assurance was paramount. This research had to be purer than Caesar's wife, and we said, "It's not going to be, because no research ever is." But probably the most valuable thing we communicated to the investigators is, Communicate everything; things are going to go wrong, but for mercy's sake, write it down so that a year from now, if there was a strange number, we can go back down a track that shows, "Yes, that was the day the power went out in Los Angeles at ten o'clock."

Now that those working relationships are in place, Dr. Sivak is comfortable that he has all the standing he needs. "We are," he sums up, "part of the working team, a team that is HEI and the advisory

Oversight Committee and the three laboratories, the data collection center at Harvard, and us."

Analyzing the data: Organizing, collecting, and interpreting the experimental findings

Will this be better knowledge to set policy? I think so — this is painstaking. Will it be the bible? I don't think so. Will it be better than what we've got? Yes.

Marcello Pagano
Harvard School of Public Health

A data collection and management center separate from the three testing centers has been established for this study. Dr. Marcello Pagano, Professor of Statistical Computing and Director of the Health Sciences Computing Facility at the Harvard University School of Public Health, is responsible for this effort, under grant with HEI.

The Data Management Center has already played a variety of important functions in these studies, including assistance in the design of the protocol, data forms, and statistical analysis, as well as planning and operation of a system for randomly assigning patients to CO levels at each visit. During the remainder of the study, the Data Management Center will be responsible for forms storage, evaluation of completeness and quality of data on the forms, statistical processing, and analysis of data.

The experiment is double-blind — neither the subjects nor investigators involved in the exercise tests will know the levels of exposures — and each subject serves as his own control. Controlled, double-blind studies are classic, considered by most scientists to be the design that yields the most objective and reliable data. Dr. Pagano, though,



Marcello Pagano

will not be code-blind, in order that data may be analyzed as they are received.

About 25 patients will be studied at each of the three centers. However, there will be an interim analysis by Dr. Pagano after about 45 patients have completed the experimental protocol. If those data are sufficient to measure effects at both 2% and 4% carboxyhemoglobin levels, with a precision that meets the analysis standards, then no more patients will be tested. If more patients must be tested to achieve statistically meaningful results, then testing will continue up to the originally-projected 25 at each center.

Dr. Pagano came to the Dana Farber Cancer Institute seven years ago, then migrated to the Computing Facility, as acting director, three years ago. Today, the computing facility has a staff of 25-30 and serves some 700 to 800 users throughout the entire medical area.

Pagano is generally positive about HEI as a concept, which he thinks is very sound. And so far, he reports, "they've been a very nice group of people to work with." He is more reluctant - as statisticians often are - to speak about the CO study before the results are in. But he seems pleased with the study design. "Insurance companies work in the large, and in the large, they're OK," he explains. "That's what statistics is all about, the large. It's signal to noise - there is signal and you've got to filter out the noise. So that's why there are 75 patients in this study. And three centers. As much to get demographics and regional variabilities as anything else." He suggests that, with 25 patients per center, there will be enough data to analyze subpopulations, as well as the aggregate. "After all," he says, smiling, "people in Los Angeles may be more laid back than people elsewhere. But we are talking about policy for the whole country."



Sheldon Murphy

Reviewing the Results: Subjecting experimental results to stringent and independent peer review

There's been a tremendous knowledge explosion, that's the real problem confronting regulators, a tremendous increase of scientific knowledge. And those interpreting it are lawyers, educators, and Congressmen. Someone needs to translate it for them - without making policy in the process.

Robert Levy
HEI Health Review Committee

The structure of HEI includes a Health Review Committee, a group of scientists whose stature equals that of the Health Research Committee and whose purpose is to provide a complete peer review process within the Institute. The Committee is chaired by Dr. Robert I. Levy, Professor of Medicine at Columbia University and former director of the National Heart, Lung, and Blood Institute. To guarantee the complete independence of the peer review, the Health Review Committee has no role in designing research projects, and no involvement with research while it is underway.

This is a division of labor that Dr. Levy refers to genially as "separation of church and state." If both processes are working properly, he notes, they will over time become mutually reinforcing without damaging the integrity of either. "The



From left, Robert Levy, Arthur Upton, and Millie Higgins

research process is separate," he explains, "but we feed into it by the nature of reviews. We then have an interactive, iterative process."

"It's wonderful when two independent committees reach the same conclusion," says HEI's Tom Grumbly. Levy would certainly agree, but does not expect such beatific harmony to be the rule, and argues that it might not serve HEI and its sponsors as well as constructive interaction over differences. He cites the CO study as a case in point. He is already aware of the structure and design of the CO study, partly from presentations made at HEI's annual scientific meeting at Asilomar, and partly because he has had to be shown documents describing them in order to prepare for the review he will eventually direct. "When we look at the results, we might say, 'You should have done this and that differently.' And the Research Committee could ignore us. But I imagine they wouldn't. Of course, we might also say, 'This is the best study ever.'"

The actual plan for review of the CO studies calls for the draft analysis and supporting documents to be scrutinized by the Health Review Committee. The Chairman will serve as the primary reviewer of the multi-center study. When he receives the draft analysis, he will direct a peer review, whose steps will include:

- Referring the draft report to appropriate experts for evaluation of the technical merits of the study, and
- A review of the study design and the methods of analysis by the Review Committee's consulting biostatistician, Dr. Paul Meier.

Dr. Levy will integrate these comments with his own analysis to prepare his report, which will then be reviewed by the full Health Review Committee. And that Committee, in turn, may make additional revisions as appropriate, and then recommend that a final report be released to the public by the Board of Directors.

In general, all HEI investigators are encouraged to publish the results of their work in peer-reviewed literature; HEI intends that the reports of the Health Review Committee be made available to the sponsors and to the public, in a manner that will not interfere with the authors' ability to publish in the peer-reviewed literature. "If we interfere with the publications process," Levy explains candidly, "we won't get the best investigators."

After publication and release of studies, the Health Review Committee remains available to assist in the interpretation of study results; however, the Committee makes no recommendation on how to apply research results to the formulation of regulatory and social policy. The task of interpretation is actually one of the chief attractions that the job has held for the Review Committee members; according to Levy,

The whole group accepted their roles because most of them were engaged in peer review, of the kind best done by the National Institutes of Health (NIH). Art Upton and I, for example, were both directors of major NIH institutes. So we've seen that process in its best and worst lights. And everybody in the group was attracted, for one thing, by an ability to bring public and private sectors together, in this time of fiscal restraint, to fund good research. Also, we wondered, could an independent party do a better job of funding research than the private sector, with its implications of conflict of interest, or the public sector, with its history of picking on the private sector? ... Finally, we were intrigued by the task of the Committee not only to review the work as peers, but to interpret it as well, to put specific works in perspective. How does this fit in the totality of knowledge, what implications does it have, how do you interpret it for those making health policy? ... Everyone on the Committee - and it's a "star" Committee - is excited about that.

The Health Review Committee is just beginning its real work, which has necessarily lagged the established and continued operation of the research program. Fiscal year 1985 was the first year that the research program achieved operation at its intended, fully-funded level, and in that year also the first fruits of research begun in earlier years reached the Review Committee. The first completed and reviewed study - Marie Amoruso's work with G6PD-deficient subjects - was released to HEI's sponsors in June and to the public in late summer. As Levy puts it, "We're the last group to



Millicent Higgins



Deborah Green



Paul Meier

get into action at HEI and we've been planning for it for the last few years; we've gotten two reports out now, but before then, we were doing a lot of dry-labbing...It's been fun developing this new paradigm," he cautions, "but our real test will come in the next year."

Perspectives on the future: Possible consequences and implications of the CO study

How do we make progress on difficult problems that aren't really solved by a one-, two-, or three-year kind of effort? I think that's one of the challenges for HEI: how do we move ourselves increasingly to a long-term orientation and with very scarce resources – a few million dollars a year – how do we "bet" with those resources to be sure of having an impact?

Roger McClellan
HEI Health Research Committee

In a branch of mathematics called projective geometry, it is axiomatic that parallel lines intersect at the horizon – just as train tracks "converge" at the point where they disappear from view. Parallel but convergent also describes the sponsors' views of HEI's future.

The EPA just recently made public its perception of the near-term future of the carbon monoxide standard with its decision to continue to enforce the standard that has been on the books for the past fifteen years. Acknowledging that no single study can be a "silver bullet," the EPA commented that it "plans to review several ongoing human

health effect studies upon their completion and, if warranted, will reexamine this decision at that time." Specifically, the Agency noted:

Several ongoing human health effect studies are being conducted by EPA and other groups to investigate the effect of CO on aggravation of angina. Subjects in these studies are being exposed to CO levels that result in blood carboxyhemoglobin levels in the range of 2.0% to 4.0%. One study is being conducted by EPA, several are being conducted at the request of EPA by the Health Effects Institute, and another study is being sponsored by the California Air Resources Board. The Health Effects Institute is an independent organization which sponsors research on automotive pollutants and is jointly funded by EPA and automobile manufacturers. The peer-reviewed results of these studies are expected by December 1986. EPA will be initiating development of a new criteria document for CO in fiscal year 1986. Thus the Agency should be in a good position to expeditiously assess the results from the above health studies, as well as other scientific evidence...



GM's Richard Kilmick



Ford's Helen Petrucci

As far as HEI's other sponsors are concerned, the general support and enthusiasm of the automobile industry for HEI have already been mentioned. However, for this report, candid executives at Ford and General Motors discussed their perceptions of HEI and environmental issues generally, and provided behind-the-scenes looks at some of their emissions testing and research activities in the Detroit area.

Ford and General Motors between them account for some 60% of the automobile industry's support to HEI. Although much clearly distinguishes these two industry giants, both firms were in complete harmony on one point: emission control systems were not marketable commodities, notwithstanding public concern for clean air.

Richard L. Klimisch, Executive Director of General Motors (GM) Environmental Activities Staff (and deputy to Betsy Ancker-Johnson, GM vice-president who was instrumental in organizing automobile industry support for HEI's launch) minced no words when asked if market pressures alone would have led GM to introduce or increase emission control systems. "No," he replied without hesitation, "that's not a marketable thing. The public won't buy that. They'll buy fuel economy. They're willing to pay something for fuel economy and they're not willing to pay for emission control." He went on to describe the discomfiting position this put him and his staff in: "We play a dual role for GM. Within the company, we're advocates for environmental and safety advances, and outside the company we have to try to deal with the demands of the advocates of more regulation. It makes us unpopular in both places."

At Ford, Helen O. Petrauskas, Vice-President of Environmental and Safety Engineering, held an equally firm opinion about the overall marketability of emission control systems per se. "It's very difficult to make the cleanliness of an automobile a selling point," she noted. "It would be very difficult for any one manufacturer to unilaterally put the equipment on a car, charge the customer \$500, and try to be competitive. You almost have to have the situation where you get a government agency saying, 'This is a requirement that everyone will meet.' I contrast that with



Certification testing at Ford. Helen Petrauskas (center) visits with staff members of the testing facility, which performs the EPA-standard certification tests for fuel economy. At left are supervisor Charles Delaharty and manager Robert Bloomfield, and at right, manager Jack Nicosky. They explained both their roles ("This is in charge of the cars, and Jack is in charge of the emissions"), and in a lighter vein, the little-noted occupational hazards they confront, such as flat tires during dynamometer trials.

something like fuel economy, because you can sell fuel economy, you can market it. In fact, I wonder why it is we have fuel economy requirements on the books, because it is a marketable item; I don't think emission controls are."

Petrauskas also made a case for the industry position that change was not nearly as difficult a problem for industry as uncertainty:

There's a misperception that we have the luxury of waiting until rules are promulgated, and then we start doing whatever we need to do to comply with those rules. Well, you'd just be out of business if you did that.

It takes the better part of five years from the start of a new car program to its completion, and that assumes you're not trying to develop a new engine and transmission at the same time. So at the outset of that program, you simply have to try to make the best assessment you can of what's likely to be required from the environmental standpoint and proceed. The later in the product development process that you make those decisions - or have to change them - the more costly it is, the more disruptive it is, and the lousier the job you'll do, from the standpoint of achieving the environmental goals without impinging on functional aspects of the product - that is, keeping the performance high and the maintenance low.

On the subject of the HEI concept, again both Klimisch and Petrauskas expressed the whole-hearted enthusiasm and support of their organizations. Klimisch noted an "informed awareness" of HEI and its activities at all levels in GM, starting with the Chairman of the Board.

Petrauskas cited remarks she had made in a 1984 speech to the Air Pollution Control Association: "As you might expect in an area as broad as 'health effects of motor vehicle emissions', there are many differences of opinion with HEI and its sponsors as to research priorities, research objectives, and the manner in which the research should be conducted. We believe these differences are helpful because, and only because, there exists an independent, non-adversarial forum in which to resolve them. Surely such an approach to research is preferable to one, all too prevalent in the past, where the regulator and the regulated commissioned research in the hope of substantiating some preconceived notion of the outcome of that research."

She enlarged on those remarks, noting that "our senior management views HEI as exemplary of the best of government and industry and academic cooperation...it's almost trite to say that industry

and environmental groups ought to find a way to work together toward a common end...everybody talks about it, but HEI is the first institution that has *done* something about it. And when I talk to our scientists, they feel - and they feel strongly - that HEI has assembled some of the best minds in the country."

Although trained as both a chemist and a lawyer, and able to speak knowledgeably about many aspects of environmental science, the articulate and gracious Ms. Petrauskas declined to comment specifically on the CO study. The outspoken Dr. Klimisch, perhaps because his training and career have been strictly scientific, was less reticent. "HEI is doing the ultimate heroic experiment," he said, in a picturesque capsule of the CO study. "Getting three labs to agree on all these techniques, and then going through a gruesome process to make sure that this was all going to be accepted. You know, my concern is that you never get a perfect experiment; you almost never get a definitive experiment. If there ever was going to be a definitive experiment, this ought to be it. But I will be surprised if it all works out perfectly."

And although Ford's non-scientist Petrauskas had declined to discuss the CO study itself, she got, figuratively speaking, the last word. She offered, after all the angst over science and the subtleties of investigative protocols, a refreshingly simple and logically unassailable way we can all help to reduce mobile source emissions: "Buy a new car as soon as possible," she urged, "this will put new and improved emission control technology on the road sooner."



Environmental research at General Motors. Dr. Ronald Williams, left, group leader and research chemist, talks to Dr. Klimisch in one of the Research Department's dynamometer laboratories. The dynamometer can simulate varied driving conditions that cause a test or experimental vehicle to produce a range of automotive emissions.

Highlights of the year

A message from Thomas P. Grumbly



Thomas P. Grumbly
Executive Director

The Health Effects Institute is a very lucky institution. Its mission is to discover and to speak the truth. It is easy to imagine how liberating that mission is. None of us who work with or for HEI ever have to wonder about the "right" things to do for the health of the Institute – the right things are to be ethical, direct, committed, and determined to find the facts wherever and whatever they may be.

The image of the simple, elegant HEI concept taking root in an often-cynical world is both exhilarating and frightening. The exhilaration stems from the hope, the ability to change the unchangeable, the deeply held belief that constructive action is possible, on an imperfect planet. If there is a birthright that is HEI's from Charles Powers, with his uncanny gift for marrying the ideal and the real, it is surely that germ of trust.

On the frightening side, the seed is still fragile and vulnerable. The task of leading the Institute is to be straightforward without being naive. Although the fears are real and appropriate, I am confident that we have the collective capability to carry out this task in an enlightened and pragmatic way.

The Health Effects Institute is a very lucky institution. Its mission is to discover and to speak the truth. It is easy to imagine how liberating that mission is.

This is HEI's first annual report – the first for both the Institute and myself. In this report, then, we are trying to convey something more than the numbers of projects, their objectives, and their finances, though these are critical to the health of the enterprise. We are trying to show our sponsors and the public a bit of the special spirit and mission that motivates all of us who have been honored to be connected with this effort.

That, of course, does not exclude the traditional stuff of annual reports – analyses of the financial

health of the institution and its accomplishments over the last year. There is much we can point to with pride. In fiscal year 1985, HEI made several long scientific and organizational strides. Substantial research resources were applied, for the first time, in a variety of institutional settings. The unique peer review system set up by the founders was finally implemented and tested. The first research report was released, and a commitment

Fiscal year 1985 marked the first year in which all components of the Institute were fully operational. . . . Research and scientific expenditures more than doubled for research in FY85 to \$5 million.



was received from the new Administrator of the EPA to institutionalize the way in which HEI's work would fit into the overall process of regulatory evaluation.

The Institute became involved in a number of issues having major scientific components with near-term relevance, including unburnt gasoline vapors, particulate trap technology, and the effects of low levels of carbon monoxide on patients with heart disease. Research priorities are gradually changing, reflecting the changing nature of diesel production at most domestic car manufacturers. HEI's original nitropyrene program was probably its most comprehensive, and consequently has required the least augmentation since its start-up. We intend to remain in the area, although our focus will shift to other aspects of the problem. Oxidant toxicity has become an important area of inquiry, as we try to understand the effects, at low levels, of nitrogen oxides and ozone. Finally, there is increasing interest in other areas, such as unregulated pollutants and exhaust products of methanol as fuel.

My perception of the highlights of fiscal year 1985 includes:

- **Operations:** Fiscal year 1985 marked the first year in which all components of the Institute were fully operational. Not only did the Health

Research Committee continue its energetic functioning, but the Health Review Committee got down to the serious business of evaluating HEI reports.

- **Budget:** Research and scientific expenditures more than doubled for research in FY85 to \$5 million, while non-scientific administrative expenses increased from \$850 thousand to about \$1 million.

- **Completed research:** Two final reports were submitted by investigators during the fiscal year. One was returned for additional work; the other, by Marie Amoroso of Rutgers, was released to the sponsors in June and to the public in late summer. We are beginning to see HEI-sponsored work appearing in the peer-reviewed literature. More than a dozen abstracts have already been received. We obviously expect to see this process accelerate rapidly during the coming year as the majority of our initial projects end, or reach the point where decisions on renewal have to be faced. We are working closely with our investigators to ensure that the reports submitted to HEI are substantially different and higher in quality than those which are ordinarily given to contractors in this field. We continue to be committed to the release of all work, but we will not release it until both the investigator and we are sure that work is well presented, well documented, and well articulated.

- **Funded research:** At the end of the fiscal year, HEI had forty projects actually underway, and seven more under negotiation. Investigators were working at thirty-five different institutions in the United States, West Germany, the United Kingdom, and Canada.

- **New research programs:** As I indicated earlier, 1985 also saw the addition of a new research area, focussing on mechanisms of oxidant toxicity. The Research Committee and the Board regard much

of this work as critical to our understanding of pollutants that continue to persist in both the U.S. and the rest of the world at sometimes troublesome levels.

● **Unregulated pollutants:** Following the articulation of the Environmental Protection Agency's policy in this area in the spring of 1984, HEI began to move into the "unregulated" pollutant arena on a number of fronts:

○ We undertook, at the request of the EPA and other sponsors who are members of the Motor Vehicle Manufacturers Association, a review of all of the data surrounding the suspected carcinogenicity of unburnt gasoline vapors;

○ We undertook, at the request of Volkswagen of America, an evaluation of the health effects of manganese as a regenerator of diesel particulate traps;

In this report, then, we are trying to convey something more than the numbers of projects, their objectives, and their finances. . . . We are trying to show our sponsors and the public a bit of the special spirit and mission that motivates all of us.

○ We solicited the views of the sponsors in a special planning request in the fall of 1984 about research needs in unregulated pollutants. As a result, the Research Committee decided in mid-June 1985, to begin a research program on the health effects of aldehydes including (a) increased susceptibility to infection, (b) carcinogenesis through interactions between aldehydes and other chemicals, and (c) pulmonary hypersensitivity to inhaled aldehydes;

○ We began a process of planning that will produce, by the fall of 1986, a comprehensive

view of the most important research problems affecting mobile sources, which, when coupled with a technology assessment also underway, will identify new research priorities.

● **Meetings and conferences:** The second Asilomar Conference was held in Asilomar, California, in January. One-hundred twenty-five scientists, invited guests, and representatives of sponsor organizations attended and shared information on the burgeoning HEI research program.

Because this is, in a literal sense, my first annual report – I joined HEI last July, in the first month of FY85 – I want to offer a few personal comments. First, I have been extraordinarily gratified by the way in which all of our sponsors have accepted the changes in day-to-day leadership at HEI. I would also like to thank very much the Board of Directors for their wisdom and support during the last year; and the Chairmen and members of our scientific committees, for both their dedication to HEI and their patience in educating me, a relative neophyte to the "mobile source" community. Our sponsors are also quite fortunate that HEI has been able to attract a high caliber of scientific and administrative staff to our effort. Not many would take the risks that an experiment like HEI entails.

Implementation is now the name of the tough game we are all in. I am committed to the success of this enterprise. One could not work for or with better people.

This talented and committed team – sponsors, scientists, staff, board, and other contributors – has made impressive progress. However much we



have accomplished so far, major challenges remain:

- We do not know what will happen when the work of the Institute challenges a strongly held belief of one of the sponsors, be it the government or any of our industrial sponsors;
- We have yet to demonstrate that the science we are funding can make a substantial contribution either to our overall body of knowledge or to policy development;
- We must continue to struggle to find the most effective way to oversee HEI projects: maximizing the possibility for good science, without stifling the independent urges of investigators;
- We must work to better understand the constantly emerging technology base in the world-wide automotive industry, so that our research is undertaken in a timely way.

We will, no doubt, have ample opportunity to confront some, if not all, of these challenges during fiscal year 1986. During this year, we expect to see:

- Continued emphasis on the scientific underpinnings of National Ambient Air Quality Standards (research on the acute effects of carbon monoxide on cardiac rhythm; studies of the mechanistic relationship between oxidant exposure and lung injury);
- Increased emphasis on "unregulated" pollutants (EPA certified HEI's role in the study of unregulated pollutants in March, 1984);
- Long-term impact on the direction of regulatory science (planning a research strategy focussed on resolving the uncertainties of human exposure to

auto emissions and the related risk, and developing the methods to undertake such research; ability to leverage other institutions);

By the end of 1986, we expect results from about two-thirds of HEI's initially funded studies. These may well provide the basis for testing HEI – itself an experiment – against its own experimental hypotheses.

- Substantial effort to increase the number and kinds of contacts between the environmentalists and the science community (in order to improve the environmental community's knowledge of HEI, its programs, and the underlying science in this area).

Most important, by the end of 1986, we expect results from about two-thirds of HEI's initially funded studies. These may well provide the basis for testing HEI – itself an experiment – against its own experimental hypotheses:

- That it is possible to clarify policy debate by creating a scientific base for difficult issues;
- That it is possible to merge public and private resources in a way that protects the public interest;
- That it is possible to attract a high caliber of scientific talent to work on "relevant" scientific issues within a supportive institutional framework;
- That it is possible to tease apart, if not ultimately separate, the roles of science and policy.

Although we have some early promising indications about the success of the HEI experiment, we have not yet demonstrated the truth of these hypotheses. There has simply not yet been sufficient time to evaluate them. But we are now in the position to verify some of them directly. In the coming year, we will begin to find out whether the experiment that is HEI will work on its own terms, and, in that context, to understand whether it can serve as a broader model for how American society can come to terms with health and environmental regulation.



Summary of research activities

Estimated completion date: 1985 1986 1987 1988

Health effects of acute levels of carbon monoxide

Parber	Mechanism of arrhythmia in a dog model		•		
Fischer	Neurotoxicity of prenatal exposure		•		
McCrath	High altitude and CO exposure in humans		•		
Poon	Atherogenesis in an animal model			•	
Slope	Individuals with elevated levels of ventricular arrhythmias			•	
Verrier	Myocardial electrical stability			•	
Whitaker	Individuals with chronic obstructive lung disease and anemia	•			
Multi-center	Acute effects of CO on subjects with coronary artery disease	•			

Health effects of low levels of carbon monoxide

Bugby	Mitogens in diesel exhaust	•			
Reibel	Metabolic activation and DNA adducts		•		
Bond	Deposition, clearance and metabolism	•			
Caroymann	DNA adducts and mitochondrial metabolism		•		
Jelliffe	Metabolic activation, DNA adducts and mitochondrial metabolism		•		
King	Metabolism and carcinogenicity		•		
Maher	Metabolism and carcinogenicity		•		
Moore	Gas and solid-phase components of exhaust, NO ₂ and SO ₂		•		
Moon	Respiratory carcinogenesis			•	
Wahl	Carcinogenicity			•	

Effects of nitrogen oxides and sulfur dioxide on lung function and airway reactivity

Jacobson	Epidemiological study in British asthmatics			•	
Kalish	NO ₂ and viral infections			•	
Ross	NO ₂ and viral infections			•	
Samet	Epidemiological study of infants in New Mexico			•	

Effects of nitrogen dioxide, ozone, and sulfur dioxide on sensitive populations

Auerman	CFD-deficient populations	•			
Duchler-Parks	Lung function in adults	•			
Kronig	Lung function in asthmatic adolescents		•		
Mandery	Lung development	•			
Mandery	Rats with emphysema		•		
Morrow/Utah	Normal and susceptible individuals		•		
Schuster	Children in an occupationally-related population		•		

Mechanisms of early markers of lung disease related to oxidative stress and injury

Brennert	Synthetic peroxidase		•		
Crandall	Active and passive epithelial transport		•		
Robinson	Epithelial injury	•			
Evans	Damage to connective tissue		•		
Johnson	Maximal lung protective inhibitors		•		
Reid	Endothelial injury		•		

Gaoping dose to target tissues produced by different types of exposure to pollutants

Gordon	Epithelial permeability	•			
Milgram	Uptake and deposition of particles	•			
Reid	Effects of periodic loading of the lung		•		
Reid	Long range of blood vessel permeability		•		

Mechanisms of oxidant injury to the lung

Reid	Biochemical and pharmacologic studies of chronic bronchitis			•	
Reid	Animal low lung protective inhibitors			•	
Reid	Chronic low-dose exposure			•	
Reid	Lung connective tissue and physiology of emphysema			•	
Reid	Epithelial injury			•	
Multi-center	Transbronchial biopsy			•	

The state of the science

It has now been nearly four years since the Health Research Committee began its task of crafting a research program that would meet the ambitious goals of the founders, i.e., "to become the nation's center for the study of the health effects of motor vehicle emissions." In the pages that follow, there are the necessarily brief descriptions of every project currently funded by the Institute, and some conservative notion of when these projects will be finished.

What have we "purchased" with this set of projects, and what should our expectations be of them? These are the questions that our sponsors, and the taxpayers and stockholders who support them, have a right and a responsibility to ask. To answer them adequately requires that we understand the scientific problem as the Research Committee came to see it, and how the Committee decided to shape the research program in response to that problem.

HEI entered the air pollution problem in mid-course, after more than a decade of experience with living under the strictures of the Clean Air Act. In setting the original National Ambient Air Quality Standards, the Congress had perhaps necessarily imposed policy judgments regarding the level of standards, but in the absence of a well-developed and reliable scientific base. The standard-setting process encouraged a mode of science that emphasized a reasonably narrow set of standardized toxicological methods to reduce uncertainty around individual air quality problems.

The Research Committee found this approach too simple in its dealing with biological systems, and too confining to provide the necessary assurance that we really understood what was occurring as emissions left the tailpipe, interacted with

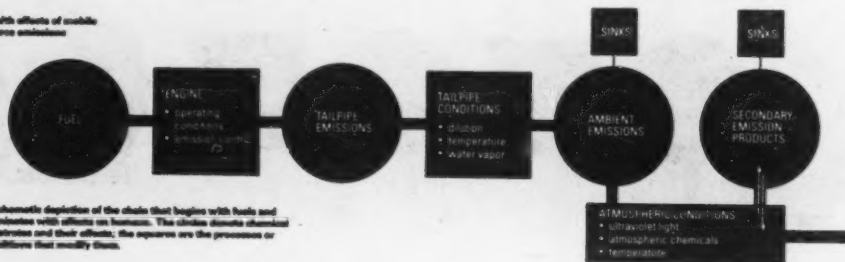
the atmosphere, entered the human pathways, and finally reached the organs of particular interest. In response to this rough flow diagram, the Committee chose a different route, one that it believed would ultimately produce a more robust scientific base, while still being relevant to the interests of the sponsors and to the needs of society.

The HEI research program developed, therefore, with at least four basic elements in mind:

- That it is necessary to have a reasonable understanding of the mechanisms of action involved when substances have effects on the human organism, in order to adequately identify the nature and magnitude of any hazard;
- That human beings are extremely variable in their response to pollutants, and that it was therefore scientifically important to fathom some of the reasons for that variability, as well as to simply identify it in some sensitive population groups;
- That it is important to try to get more than one or two "snapshots" of a problem; i.e., it is important to fund a variety of efforts that attempt to look at various aspects of a pollutant's effects in order to make some sense about what might be happening;
- That it is important to stimulate new techniques in assessing hazards through emphasizing a basic biological approach that some scientists have identified with the name of "molecular epidemiology"; such an approach would attempt to identify the dose of chemicals that actually reach a given organ, and any markers related to that dose which would serve as early warnings of disease.

In pursuing this approach, the Committee has not lost sight of the necessity of using existing tech-

Health effects of mobile source emissions



A schematic depiction of the chain that begins with fuels and culminates with effects on humans. The circles denote chemical substances and their effects; the squares are the processes or conditions that modify them.

niques to meet the real problems that government and industry must solve on a day-to-day basis. Indeed, it is in the attempt to merge regulatory relevance with the development of an up-to-date scientific base that we hope to show that HEI is creatively different. There is, therefore, no easy separation of HEI science into that which is relevant for near-term regulatory needs, and that which is required for long-term scientific development. In the new "regulatory science", old terms like "applied" and "basic" may no longer be the most interesting.

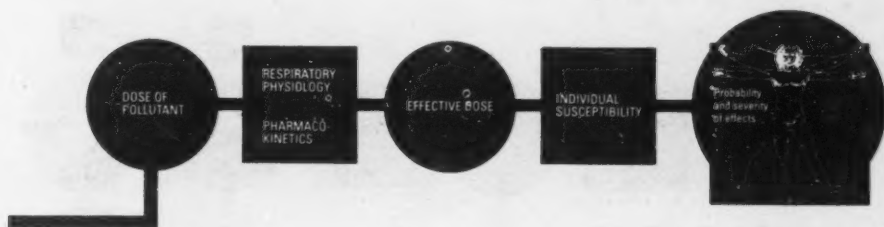
To implement the strategy of combining new principles with old problems, the Committee and the Board expressed confidence in the workings of the scientific "free market." The Committee defined problems in its Requests for Applications that were of both regulatory and scientific interest, and then left it to the scientific community to develop solutions. The Committee has funded in its first four years only about 15% of the applications it received, and has mixed its choices in terms of methods and investigators. HEI has attracted a number of scientists into this area who did not work in it before. It has funded both established investigators and newcomers.

The upshot of this is that the classifications by "program" area that one sees have, by necessity, a certain artificiality about them. For administrative as well as analytic ease, it is necessary to think of the projects in "chunks." In a very real way, however, the HEI program has a kind of coherence that, we believe, will become its major strength. Projects focussed on one pollutant or using one method will end up influencing others. While the Committee finds it increasingly useful to think about the program using the risk assessment

framework suggested by the National Research Council, it remains committed to a flexible approach in project selection that maximizes the potential for creativity.

For administrative purposes and to emphasize its mission, HEI uses the mechanism of contracts to support its scientific investigators; its intent, however, is to come as close as possible to the selection system that has produced much of what is considered best in American science, the investigator-initiated, peer-reviewed, competitive process that is characteristic of the National Institutes of Health and the National Science Foundation.

It is only two years since actual research has begun under the auspices of HEI. Therefore, we are still a long way from being able to evaluate the program fairly. What we can say is that a small community of scholars seems to be in the making that crosses sectorial lines, and that was largely nonexistent four years ago. From this community, we expect few "silver bullet" studies that will transform the way in which we think. Science is an iterative process, and, in this area, we are still building the conceptual framework that will permit us to know where to make our best choices. Some of the work described in the following pages will undoubtedly be modified and possibly reoriented. Other studies will end as they are evaluated. New areas will be identified. In the coming year, several studies will come to fruition that will undoubtedly have near-term regulatory consequences. In all of this we hope that the hallmark of HEI science will be an attention to the mission of the Institute, with a firm commitment to quality in conceptualization as well as implementation.



Research abstracts

Health effects of low levels of carbon monoxide

- J.P. Farber
University of Oklahoma

Carbon monoxide and lethal arrhythmias

Completion date: 1986
(with possibility of further funding)

The objective of this study is to determine whether exposure to carbon monoxide increases the susceptibility to sudden cardiac death. Conscious dogs with a healed myocardial infarction are being studied. Initially experiments are being performed after exposure leading to carboxyhemoglobin concentrations of 10%. Higher or lower levels will then be used depending on the results.

- L.D. Fochter
Johns Hopkins University

Neurotoxicity of prenatal carbon monoxide exposure

Completion date: 1986

This study attempts to determine whether prenatal exposure to levels of CO related to actual ambient exposures can cause disruption in neurological transmission functions in the brains of fetal rats. The project also examines whether CO exposure alters brain cell number and size.

- S.M. Horvath
University of California at Santa Barbara

Cardiorespiratory responses to maximum work during carbon monoxide exposure at high altitude

Completion date: 1986

This study is designed to determine the combined effects of CO and high altitude on work capacity. Both types of exposure result in decreased availability of oxygen to tissues, and both result in decreased ability to do work. However, there are differences in physiological responses to each, and the combined effects have not been well studied. Dr. Horvath's research will determine whether CO and high altitude produce additive, or greater than additive, effects on work capacity and whether there are any gender-related differences in response.

- J.J. McGrath
Texas Tech University

Cardiovascular effects of chronic carbon monoxide-altitude exposure

Completion date: 1987

This study in rats, in conjunction with a human clinical study underway by Dr. Horvath, will provide information on the combined effects of CO and high altitude. An extensive analysis of the cardiovascular system will be undertaken after prolonged exposure to CO, to simulated high altitude (decreased air pressure), and to both, as well as to clean air at normal pressure. To determine whether any cardiovascular changes that are seen are adaptive, some of the animals exposed to CO and/or high altitude will be challenged with an acute CO exposure and then evaluated.

- Multi-center carbon monoxide study

Clinical studies

E.R. Blecker
S.O. Gottlieb
The Johns Hopkins University
B.R. Chaitman
T.E. Dahms
St. Louis University
J.D. Hackney
R.O. Selvester
Rancho Los Amigos Hospital

Acute effects of carbon monoxide on individuals with coronary artery disease

Completion date: 1986

Investigators at three institutions are participating in a study of the acute effects of carbon monoxide in human subjects with angina pectoris. This study is designed to replicate and extend studies that have shown a decrease in the length of exercise time prior to the onset of angina in patients exposed to CO. Because this effect was demonstrated at low levels of exposure, these results have taken on considerable importance in discussions of the national ambient air quality standard for CO.

At each of the three centers, 25 subjects will be studied using identical protocols. Effects are to be measured using a standard exercise protocol after exposure to normal air

and to air containing elevated levels of CO that will produce carboxyhemoglobin levels of about 2.0% and about 4.0% in each subject. Parameters to be studied include time to onset of angina and electrocardiographic changes; a fuller description of this study is provided elsewhere in this book.

Supporting studies

M. Pagano
Harvard School of Public Health
Data Management Center for multi-center study: providing data collection, statistical processing, and data analysis.

A. Sivak
Arthur D. Little, Inc.
Quality assurance for multi-center study: providing quality assurance at all sites involved in study.

D. Stevenson
Stanford University
Consulting on carboxyhemoglobin measurements for multi-center study: confirming accuracy of measurement of carboxyhemoglobin levels in blood samples and calibration standards as requested by principal investigators.

- A. Penn
New York University Medical Center

Definitive determination of the atherogenic potential of inhaled carbon monoxide

Completion date: 1987

This study is designed to determine the effects of chronic CO exposure in the development of atherosclerotic plaques in cockerels. This will be evaluated in animals given a normal diet and in animals given a diet with mildly elevated cholesterol levels which promotes atherogenesis. The investigators will also determine whether CO exposure affects the regression of pre-existing plaques.

- D.S. Sheps
University of North Carolina

Acute effects of carbon monoxide on cardiac rhythm

Completion date: 1988

This is a clinical study of the effect of CO exposure (4% and 6% carboxyhemoglobin) on the occurrence of arrhythmias in subjects with elevated levels of ventricular arrhythmias. Exposure to either CO or air will be followed by a bicycle exercise test. A Holter monitor will be used to record the electrocardiogram for 24 hours before the exposure session.

- R.L. Verrier
Harvard School of Public Health

Acute effects of carbon monoxide on cardiac electrical stability

Completion date: 1987
(with possibility of further funding)

This is a study of the effects of acute exposure to CO on myocardial electrical stability in dogs. In addition to evaluating normal animals, dogs with various experimentally produced models of myocardial ischemia will be studied. The investigators will look for effects at 10% to 20% carboxyhemoglobin, but will study lower levels if effects are found.

- J.L. Whittenberger
University of California at Irvine

Effects of short-term exposure to carbon monoxide

Completion date: 1986

This is a clinical study of the effect of CO exposure on exercise performance in two groups that may be particularly susceptible to the effects of CO because of decreased ability to deliver oxygen to cells. These groups are individuals with chronic obstructive lung disease and individuals with anemia. Carboxyhemoglobin levels of 6% are being used.

Health effects of emissions from diesel vehicles

- S. Bagley
Michigan Technological University

An investigation of the effect of a ceramic trap on chemical mutagens in diesel exhaust

Completion date: 1985

This study makes a comparison of the biological effects of emissions from diesel engines in the presence and absence of ceramic particulate traps. Dr. Bagley will examine the soluble organic fraction of diesel particulate samples collected from medium-duty diesels with and without ceramic particulate traps. The samples will be tested for biological activity in the Ames *Salmonella* mutagenicity test and active subfractions will be further analyzed, particularly for identification of highly mutagenic nitroaromatic compounds.

- F.A. Beland
University of Arkansas

Metabolic activation and DNA adducts of dinitropyrenes

Completion date: 1986

Dinitropyrenes, found in diesel exhaust, are among the most mutagenic compounds in bacteria. Dr. Beland is studying the enzymes that metabolize nitropyrenes and the relationship among metabolism, DNA adduct formation, and mutagenesis.

- J.A. Bond
Lawrence Inhalation Toxicology Research Institute

Disposition and metabolism of free and particle-associated nitropyrenes after inhalation

Completion date: 1985

The purpose of this project is to develop understanding of the fate of 1-nitropyrene in the lungs. Dr. Bond has examined the amount of inhaled 1-nitropyrene deposited in the lungs of rats, its distribution through the body, and its excretion. Some animals were exposed to a fine aerosol of the chemical alone, others to 1-nitropyrene attached to diesel particles. Comparison with other HPLC studies may reveal how this process affects carcinogenic activity.

- J.D. Groopman
Boston University School of Public Health

Interaction of nitropolynuclear aromatic hydrocarbons with DNA detected by monoclonal antibodies

Completion date: 1985

This study attempts to develop monoclonal and polyclonal antibodies which recognize the covalent adducts formed between nitropyrenes, and DNA and proteins. These antibodies would be useful in assessing nitropyrene binding to DNA in humans.

- A. M. Jeffrey
Columbia University

Metabolic activation of nitropyrenes and diesel particulate extracts: studies on their biological effects with respect to estimating human risk

Completion date: 1986

This project examines the interaction of nitropyrene with mouse, rat, and human DNA. To this end, Dr. Jeffrey has prepared monoclonal antibodies which recognize nitropyrene-modified DNA. These studies are being extended to dinitropyrenes as well as to extracts of diesel particles.

- C.M. King
Michigan Cancer Center

Metabolism and biological effects of nitropyrenes and related compounds

Completion date: 1986

Dr. King has previously reported that subcutaneous injection of 1-nitropyrene in rats induces mammary cancer. In this project, he is studying the effect of route on the carcinogenicity of a number of mono- and di-nitropyrenes, as well as the metabolism of nitropyrenes in mammary epithelium *in vitro*.

- V.M. Maher
Michigan State University

Studies on the metabolism and biologic effects of nitropyrene and related nitropolycyclic aromatic compounds in diploid human fibroblasts

Completion date: 1986

The purpose of this investigation is to study the toxic, mutagenic, and transforming effects of nitropyrenes and other related chemicals in cell cultures in the laboratory. Dr. Maher is comparing the cytotoxicity of nitropyrene in normal cells with cells that are deficient for DNA repair. She is also investigating the frequency of cell transformation and the extent of DNA adduction *in vitro* with nitropyrenes.

- U. Mohr
The Fraunhofer Institute

A possible co-carcinogenic effect of nitrogen dioxide and sulphur dioxide on the respiratory tract

Completion date: 1986

Dr. Mohr has observed an increased respiratory tumor rate in Syrian hamsters exposed to carcinogens and "particle-free" diesel exhaust. This research focuses on the possible co-carcinogenic effects of the irritant gases or the gas-phase organics present in diesel exhaust. In the present study, hamsters are being exposed to diethyl nitrosamine and to NO₂ and SO₂.

- R.C. Moon
IIT Research Institute

Respiratory carcinogenesis of nitroaromatics

Completion date: 1987

This study examines respiratory carcinogenicity of nitropyrenes by directly instilling the

compound into the tracheae of hamsters. Dr. Moon is also investigating synergistic interactions between nitropyrenes and other compounds such as benzo-a pyrene.

- R.K. Wulff
Lavalin Inhalation Toxicology Research Institute
Carcinogenicity of inhaled nitropyrene aerosols

Completion date: 1987

This study will provide information on how association of 1-nitropyrene with particles inhaled into the lungs affects its carcinogenic activity. Dr. Wulff is studying the carcinogenicity of nitropyrenes in rats by exposing the animals to nitropyrene aerosols alone as well as in combination with gallium oxide particles. He will also investigate the effect of simultaneous exposure of sulphur dioxide to examine whether the development of lung tumors is enhanced.

Effects of nitrogen oxides on lung development and susceptibility to infection

- M. Jacobsen
Institute of Occupational Medicine

Respiratory infections in coalminers exposed to nitrogen oxides

Completion date: 1987
(with possibility of further funding)

The purpose of this study is to determine whether exposure to nitrogen oxides in coalminers is associated with increased susceptibility to pulmonary infection. Two approaches are used. First, respiratory infection frequency will be determined by questionnaire in two groups of miners with exposure to different nitrogen oxide levels. Second, nitrogen oxide exposure of coalminers who have an increased susceptibility to pulmonary infection will be determined retrospectively.

- G.J. Jakob
The Johns Hopkins University

Nitrogen dioxide induced increased susceptibility and severity of respiratory infections

Completion date: 1987

This project examines the effects of NO₂ on respiratory infections in mice caused by

several different bacteria and viruses. The infection agents chosen represent patterns of disease and involve different defense mechanisms in the body. The cause of disease will be correlated with the replication or killing of the infectious agents and the activity of the host defense mechanisms.

- T. Kulle
University of Maryland

Susceptibility to virus infection with exposure to nitrogen dioxide

Completion date: 1987

In this study, Dr. Kulle is examining the effects of NO₂ on susceptibility of adult males to infection by a non-virulent strain of influenza virus. Both respiratory symptoms and immunological response are being studied.

- R. Rose
New England Deaconess Hospital

Nitrogen oxides and susceptibility to viral respiratory infection

Completion date: 1987

This study examines the effect of NO₂ on infection by murine cytomegalo virus in mice. Dr. Rose is investigating the details of host defense mechanisms, in particular macrophage activity.

- J. Samet
University of New Mexico

Nitrogen oxides and respiratory infections in infants

In a prospective epidemiological study, Dr. Samet will examine household NO₂ levels associated with gas or electric stoves and follow the state of infant's health. A feasibility study for this project is near completion, and a proposal for a full study is under review.

Effects of nitrogen oxides, ozone, and diesel exhausts on susceptible populations

- R.L. Ammend
University of Medicine and Dentistry of New Jersey, Rutgers Medical School

Estimation of risk of glucose 6-phosphate dehydrogenase deficient red cells to ozone and nitrogen dioxide

Completion date: completed

The objective of this study was to determine whether exposure to ambient levels of ox-

idant gases posed a significant health risk to individuals with glucose 6-phosphate dehydrogenase (G6PD) deficiency. The A- variant of G6PD-deficiency is a sex-linked inheritable enzyme deficiency. Individuals with this disorder may be susceptible to significant hematologic effects when exposed to ozone or NO₂ at ambient levels. To attempt to quantify any health risks, *in vivo* studies treated G6PD-deficient mice with known oxidant drugs or exposed them to oxidants at ambient levels for 2-3 hours. Red cell glutathione levels following the exposures were then compared. *In vitro* studies compared normal and G6PD-deficient human red cells after exposure to oxidants and hemolytic drugs.

- D.M. Drechsler-Parks
University of California at Santa Barbara

Effect of nitrogen dioxide, ozone, and peroxyacetyl nitrate on pulmonary and metabolic function

Completion date: 1985

Dr. Drechsler-Parks is doing human clinical studies to determine whether the pulmonary function effects of exposure to mixtures of several air pollutants are equivalent to those predicted by combining the effects of the individual pollutants. The pollutants being used are O₃, NO₂, and peroxyacetyl nitrate (PAN). The study is also designed to obtain data on the responses of young women and of men and women over 50 years of age, sub-populations which have been largely ignored in previous investigations. The final report is currently in the HEI review process.

- J.Q. Koenig
University of Washington

The effects of ozone (and nitrogen dioxide) on lung function in asthmatic adolescents

Completion date: 1986

The purpose of this project is to investigate the effects of short-term inhalation exposures to ozone or nitrogen dioxide on lung function in adolescent subjects. Two groups of adolescents aged 11-18 are participating: healthy adolescents who have no signs or symptoms of allergic disease, and ten asthmatic adolescents who have a history of atopic extrinsic asthma. Concentration for each gas is 0.12 parts per million, a level that people may encounter outdoors. Experiments will be carried out at rest and during exercise.

- J.L. Mauderly
Levelle Inhalation Toxicology Research Institute

Influence of pre-existing pulmonary emphysema on the health effects of inhaled nitrogen dioxide and diesel exhaust

Completion date: 1986

In this study, young adult rats are exposed to dilute whole diesel exhaust, to NO_2 , and to clean air for two years. Prior to exposure, in one half of the population, elastase was intratracheally instilled to induce emphysema. By evaluating functional, structural, and biochemical endpoints at six-month intervals, it will be possible to evaluate whether subjects with pre-existing chronic lung disease are more sensitive to the effects of diesel exhaust or oxidant inhalation.

- J.L. Mauderly
Levelle Inhalation Toxicology Research Institute

Effects of inhaled nitrogen dioxide and diesel exhaust on the developing lung

Completion date: 1985

This research attempts to determine whether early exposure to emission products of mobile sources adversely affects the development of the lung and whether this effect persists. Both newborn and adult rats are exposed to NO_2 to dilute whole diesel exhaust, and to clean air for six months. Pulmonary function, structure, and biochemistry are being evaluated to determine whether this early exposure leads to developmental defects in lung structure, particle clearance and immunological defense mechanisms that suggest that the very young are an especially susceptible population. Comparison between animals exposed to NO_2 and those exposed to whole diesel exhaust, a complex gas-particle mixture, should provide additional indicators of the role of specific exhaust constituents and of whole exhaust.

- P.E. Morrow and M.J. Utell
University of Rochester

Responses of susceptible populations to nitrogen dioxide

Completion date: 1986

This research evaluates the effects of human exposure to moderate levels of NO_2 . Pulmonary function tests will be performed on adult subjects exposed for four hours at 0.3 parts per million while they are performing intermittent exercise on a bicycle ergometer to simulate normal light outdoor activity and breathing rates. In addition to normal adults,

a number of groups potentially susceptible to air pollutants are being studied. These include individuals with asthma and chronic obstructive pulmonary disease.

- M.B. Schenker
University of California at Davis

Biologic monitoring of human sensitivity to diesel exhaust exposure

Completion date: 1986

This study will measure bacterial mutagenicity in urine from railroad workers exposed to diesel exhaust. Variations in mutagenicity of the workers' urine could be influenced by smoking and dietary habits as well as by diesel exposure. Development of evaluation methods is extremely important because the accurate assessment of exposure is vital to meaningful dose-response conclusions in epidemiological studies.

Identification of early markers of lung disease related to mobile source emissions

- P.A. Bromberg
University of North Carolina

Effects of ozone on airway epithelial permeability and ion transport

Completion date: 1986

This study examines the effect of ozone on the permeability and bioelectric properties of guinea pig trachea. Following exposure, tissue is examined both in the intact animal and *in vitro*. Dr. Bromberg is also conducting studies in guinea pigs aimed at a better understanding of the time course for ozone effects and the phenomenon of "adaptation" seen in humans who are repeatedly exposed to ozone.

- E.D. Crandall
University of California at Los Angeles

Effects of mobile source emissions on alveolar epithelial barrier properties

Completion date: 1986

This research investigates the effects of NO_2 on alveolar epithelial type II cells *in vitro*. The study is focused on the transport and permeability characteristics of the cells when cultured as monolayers. Future plans include adapting the exposure methodology to construct a dose-response curve with the intention of working at near ambient levels of NO_2 .

The effect of adding protective factors to the medium, such as reduced glutathione and vitamin E, is also being studied. Other biochemical and morphological investigations are planned to delineate the changes resulting from NO_2 exposure in these cell monolayers.

- C.D. Eskelson
University of Arizona

Pulmonary lipotropic factor

Completion date: 1985

Earlier research by Dr. Eskelson demonstrates that homogenates of lung tissue contain two chemicals that affect the production of fatty substances by liver cells: one that stimulates fat production and one that inhibits. Furthermore, the evidence suggests that these chemicals are released into the blood stream when lungs are damaged by toxic chemicals. If specific for damaged lung, this phenomenon could be the basis for a blood test for toxic damage to the lung. On the other hand, if the same effect occurs when many other body tissues are damaged, it may have little practical diagnostic use. Dr. Eskelson has explored the specificity of the two chemicals for lung tissue and obtained information on their chemical nature. The final report for this project is in review.

- J. Evans
University of Vermont

Early markers of lung injury

Completion date: 1986

This project attempts to identify biochemical markers that can be used as oxidant-induced indicators of lung injury. The intention is to make markers available for analysis by non-invasive methods to assure their usefulness in longitudinal animal studies and their future application to the human population. The markers selected are available in urine, serum, and/or lavage fluid, and primarily reflect effects on connective tissue in the lung. In addition, the investigators will gather data on pulmonary function and morphometry.

- D.A. Johnson
East Tennessee State University

Effects of ozone and nitrogen dioxide on human lung proteinase inhibitors

Completion date: 1986

The purpose of this study is to determine whether ozone exposure inactivates the lung's natural inhibitors of proteinase activity, alpha-1-proteinase inhibitor. Inactivation of these inhibitors could produce increased

since probability to the development of emphysema. Dr. Johnson has measured inhibitor levels in the blood plasma of humans exposed to 0.5 parts per million O_3 for four hours and is also studying biochemical alteration of the inhibitors exposed to O_3 *in vitro*.

- J.M. Patel
University of Florida

Biochemical and metabolic response to nitrogen dioxide-induced endothelial injury
Completion date: 1986

This study examines the effects of NO_2 on endothelial cells in culture in order better to understand oxidant injury in the lung. The endothelial cells are derived from pig aorta and pulmonary artery, but are used as models for endothelial cells of lung capillaries. The *in vitro* system enables the isolation of effects on a single cell type. Most studies of oxidant injury have concentrated on epithelial cells which line the airways, but endothelial cells have also been shown to be sensitive to oxidant injury. Among the biochemical changes being measured are the activities of a variety of enzymes that have protective antioxidant functions, but whose activity is thought to be altered by exposure to oxidants. Oxidative damage to the cell membrane is assessed by measuring the fluidity of the membrane and its transport properties. Changes in cell shape, size, and number are also being evaluated. These measurements on a homogeneous population of cells will enable an exploration of mechanisms of injury and ultimately lead to an understanding at the molecular level. Correlations between *in vivo* and *in vitro* effects on endothelial cells will be established.

Evaluating dose to target tissues produced by different types of exposure to pollutants.

- T.T. Crocker
University of California at Irvine

Transport of macromolecules and particles at target sites for deposition of air pollutants
Completion date: 1985

This project attempts to determine the relative susceptibilities to pollutant injury of different regions of the respiratory tract, specifically, the nose, trachea, and bronchoalveolar zones. The pollutants under investigation are O_3 , NO_2 , and formaldehyde given

individually or in select combinations. The determinant of injury is the transepithelial transport rate of specific molecules administered *in vivo* rats subsequent to exposure. Transport is measured either from the epithelium to the bloodstream or in the opposite direction. Electron microscopy has been used to help identify more specifically the routes to transport. The final report for this project is in review.

- M.T. Kleinman
University of California at Irvine

The effects of exercise on the dose and dose distribution of inhaled automotive pollutants
Completion date: 1987

This project studies dogs to determine how factors such as exercise, ventilatory pattern, and route of inhalation modify pulmonary deposition and distribution of pollutants from automobile exhaust. The pollutants are ammonium nitrate aerosol, formaldehyde vapor, NO_2 , and carbon aerosol presented singly or in various combinations. The study examines penetration of inhaled pollutants to respiratory targets altered by changes in ventilation rate, tidal volume, route of entry, and composition of the atmosphere. The project also studies breathing patterns altered by inhaled pollutants, and increased penetration of pollutants to target sites. This project will especially further knowledge in two areas: characteristics of gaseous uptake in the respiratory tract, and pollutant behavior when part of a mixture.

- M.B. Snipes
Lovelace Inhalation Toxicology Research Institute

Effect of particle loading of the lung on clearance kinetics and particle microdistribution

Completion date: 1985

The aim of this project is to determine the extent to which long-term diesel particle loading of the lung affects (1) pathways and rates of clearance of subsequently inhaled radiolabeled aerosol, and (2) the tissue distribution of the chronically administered diesel particles. These studies will help determine whether altered clearance in humans, if present, is attributable to inhaled material

delivered to pulmonary target sites. It will also help improve our understanding of previous animal studies in which large doses were administered. To provide a range of inherent clearance efficiencies, both rats, which have rapid clearance, and guinea pigs (slow) will be used. Clearance rates for guinea pigs approximate human clearance rates better than do those of rats.

- C.P. Yu
State University of New York at Buffalo

Determination of lung doses of diesel exhaust particulates

Completion date: 1986

This project seeks to apply mathematical and computer models to characterize the deposition pattern of inhaled diesel particles in the respiratory tract of humans and animals. The goal is to provide greater predictability concerning respiratory tract exposure to diesel exhaust. Data on the physical characteristics of automobile diesel exhaust will first be collected from published references, analyzed, and formatted for input to the model(s). Deposition patterns for healthy human adults under different breathing conditions will be calculated. A key feature of this project is the extension of results in adults to younger age groups. Finally, laboratory species (rats, hamsters, guinea pigs) will be subjected to the same analyses. It is reasonable to expect that deposition of the particles, mainly aggregates under 0.3 micrometers, will be governed by diffusion and interception whereas sedimentation and impaction will play minor roles.

Mechanisms of oxidant injury in the lung

- B.A. Freeman
University of Alabama, Birmingham

Oxidant injury to the alveolar epithelium: biochemical and pharmacologic studies

Completion date: 1988

This project explores the specificity of antioxidants in protecting the lung against oxidant injury. Dr. Freeman will expose rats or cultured epithelial cells to either hyperoxia or O_3 . Subsequently, animals will be given antioxidants enclosed in aerosolized liposomes. Measures of oxidant injury will include: in whole animals, survivorship in 100% O_2 and epithelial permeability to solutes; and in cultured cells, cell viability, lipid oxidation,

glutathione oxidation, and membrane biophysical characteristics. The study will compare hyperoxia and O_3 injury, and determine which anti-oxidant protects against injury. In this way, the research can provide clues to the mechanism of injury, localize cell type and subcellular distribution of liposome-packaged molecules, and determine if alterations in membrane proteins occur during oxidant injury.

- D.A. Johnson
East Tennessee State University

Oxidant effects on rat lung proteinase inhibitors

Completion date: 1988

This study aims to establish the rat as a usable model for the effects of oxidants on lung proteinase inhibitors. Humans have two proteinase inhibitors which protect pulmonary elastin from the degradative action of leukocyte elastase. Alpha-1-proteinase inhibitor (alpha-1-PI) is found in the alveolar region, as well as the plasma. Bronchial leukocyte proteinase inhibitor (BLPI) is produced locally in the upper airways. Cigarette smoke and O_3 are known to inactivate these inhibitors. Dr. Johnson proposes to: purify, characterize, and produce antibodies to rat alpha-1-PI, determine what effects *in vitro* exposure to O_3 has on the molecule, isolate the rat analog to human BLPI, and study the effects of chronic *in vivo* exposure to O_3 , NO_2 , or diesel emission on rat alpha-1-PI activity in lavage and serum samples.

- J. Last
University of California at Davis

Synergistic effects of air pollutants: ozone plus a respirable aerosol

Completion date: 1988

This project examines whether O_3 and sulfate aerosols synergistically injure the lung, and whether injury is mediated by free radicals. Dr. Last has shown previously that toxic effects of O_3 (histologic lesions at the alveolar duct region and increased collagen synthesis) are enhanced when administered with ammonium sulfate. These studies were done at very high levels of oxidant and aerosol. This research will study whether synergy occurs at

or near ambient concentrations of oxidant and sulfate aerosols, and will investigate the role of free radicals in increased collagen synthesis.

- G.L. Mechanic
University of North Carolina

Biochemistry of lung connective tissue and physiology of emphysema

Completion date: 1988

This project will track the progression of emphysema in a strain of mouse prone to this disease, and then determine the manner in which exposure to NO_2 may aggravate the disease process. Specifically, Dr. Mechanic will relate biochemical metabolic defects in lung collagen and elastin to the observed abnormalities in lung structure and function, with emphasis on the amounts and alterations of intermolecular crosslinks. This research will expand our understanding of the role of inherited abnormalities of connective tissue synthesis in the pathogenesis of emphysema following environmentally-induced lung injury.

- K.A. Tanswell
University of Western Ontario

Detection of paracrine factors in oxidant lung injury

Completion date: 1987

This project will identify cellular growth factors that are produced in the lung after exposure to O_3 or hyperoxia. The blood plasma from rats will be collected and assayed for growth-promoting activity against purified populations of type II pneumocytes, lung fibroblasts, and pulmonary endothelial cells. Dr. Tanswell also plans to isolate and characterize the growth-influencing factors.

- M.J. Utell and P.E. Morrow
Strong Memorial Hospital

Mechanisms of nitrogen dioxide toxicity in humans

Completion date: 1988

This research will identify the mechanisms of toxicity during NO_2 exposure, as well as evaluate short-term respiratory and clinical effects. The NO_2 exposure design will incorporate multiple peak levels on a continuous background concentration of NO_2 . Moderate exercise will be performed on a bicycle ergometer during periods of peak exposures.

Alterations in lung function will be detected by pulmonary function tests designed to detect changes in lung function before symptoms occur. Performance of bronchoalveolar lavage after NO_2 exposure will permit a new approach for the assessment of mechanisms of toxicity of these pollutants in humans. Influx of inflammatory cells, alterations of protein content and enzyme activity, and functional activity of alpha-1-proteinase activity will be measured in lavage fluid after the chamber study. The relationship between NO_2 exposure and enhanced susceptibility to infection will be evaluated by measuring lavaged leukocyte antiviral activity.



To the Board of Directors of The Health Effects Institute:

We have examined the balance sheets of The Health Effects Institute (a District of Columbia nonprofit corporation) as of June 30, 1985 and 1984 and the related statements of activity and changes in fund balance and changes in financial position for the years then ended. Our examinations were made in accordance with generally accepted auditing standards and, accordingly, included such tests of the accounting records and such other auditing procedures as we considered necessary in the circumstances.

In our opinion, the financial statements referred to above present fairly the financial position of The Health Effects Institute as of June 30, 1985 and 1984 and the results of its activities and the changes in its financial position for the years then ended, in conformity with generally accepted accounting principles applied on a consistent basis.

Our examinations were made for the purpose of forming an opinion on the basic financial statements taken as a whole. Exhibits I and II are presented for purposes of additional analysis and are not a required part of the basic financial statement. This information has been subjected to the auditing procedures applied in our examination of the basic financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic financial statements taken as a whole.

August 9, 1985
Boston, Massachusetts

Arthur Andersen & Co.

Balance sheets

For the years ending June 30:

Assets

	1985	1984
Cash	\$ 943,002	\$ 458,940
Grants and contributions receivable (Note 1)	421,691	9,197
Advances on research contracts	83,324	207,088
Office equipment, at cost, less accumulated depreciation (Note 1)	65,064	24,117
Prepaid insurance and other assets	14,963	5,165
	<u>\$1,528,044</u>	<u>\$ 704,507</u>

Liabilities and fund balance

Accounts payable:		
Research grants	\$1,060,940	\$ 388,571
Other	92,979	21,952
Accrued expenses	35,356	20,629
Deferred support (Note 1)	242,477	219,303
Commitments (Note 2)		
Fund balance (Note 1)	96,293	54,052
	<u>\$1,528,044</u>	<u>\$ 704,507</u>

The accompanying notes are an integral part of these financial statements.

Statements of activity and changes in fund balance

For the years ending June 30:	1985	1984
Revenue and support:		
Grants and contributions (Note 1)	\$5,988,120	\$2,504,337
Interest income	50,735	30,077
Total revenue and support	<u>\$6,038,855</u>	<u>\$2,534,414</u>
Program, general and administrative expenses (Exhibit 1):		
Scientific services		
Research contracts	\$4,698,132	\$2,087,952
Consultants	288,766	237,601
Salaries and employee benefits	433,110	231,217
Travel	210,394	154,067
Other expenses	366,212	205,276
	<u>\$5,996,614</u>	<u>\$2,916,113</u>
Excess (deficit) of revenue and support over expenses	\$ 42,241	\$ (381,699)
Fund balance, beginning of period	54,052	435,751
Fund balance, end of period	<u>\$ 96,293</u>	<u>\$ 54,052</u>

Statements of changes in financial position

For the years ending June 30:	1985	1984
Cash was provided by:		
Grants and contributions received	\$5,599,268	\$2,545,143
Interest	54,695	30,077
Total sources of cash	<u>\$5,653,963</u>	<u>\$2,575,220</u>
Cash was used for:		
Cash expenditures for operating expenses	\$5,115,482	\$2,749,017
Purchases of office equipment	54,419	5,441
Total uses of cash	<u>\$5,169,901</u>	<u>\$2,754,458</u>
Increase (decrease) in cash balance	<u>\$ 484,062</u>	<u>\$ (179,238)</u>

The accompanying notes are an integral part of these financial statements.

Notes to financial statements: June 30, 1985

Note 1: Operations and accounting policies: The Health Effects Institute (the Institute) is a non-profit organization incorporated May 20, 1980, for the purpose of researching and reporting on the health effects of motor vehicle emissions. The organization is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code.

Support for the Institute consists principally of unrestricted contributions from motor vehicle engine manufacturers (industry) and grants from the U.S. Environmental Protection Agency (EPA). It is the intent of the Institute that industry and the EPA share equally in the overall support of the Institute's activities.

The following is a summary of the significant accounting policies applied by the Institute in the accompanying financial statements.

a: Revenue and support: Grants received and receivable by the Institute from the EPA are deemed to be earned and are reported as support to the extent that expenses have been incurred during the period for the purposes specified by the EPA. The difference between funds received from the EPA and expenses incurred which are allocable to the EPA, results in deferred or accrued support.

Industry contributions are collected quarterly and in advance based on anticipated expenditures for the succeeding quarter. Contributions are reported as support in the fiscal year to the extent earned as described above. Those contributions specified for future fiscal year expenditures are deferred and reported as support in the period to which they relate.

The Institute has received grants and contributions to be used for the establishment, operation and administration of its research program as follows:

	EPA	Industry
Cumulative support since inception	\$5,062,253	\$5,304,727
Less - Support related to fiscal 1986 activities	—	242,477
Cumulative support recognized from inception through fiscal 1985	\$5,062,253	\$5,062,250
Less - Cumulative expenses since inception	5,062,253	5,062,250
Cumulative support in excess of expenses	\$ —	\$ —

EPA funding of the Institute has consisted of two grants. Grant 1 consisted of a letter of credit for \$3,550,000 which expired on June 30, 1985. This grant was fully utilized prior to that date. Additional funding was provided by Grant 2, which consists of a letter of credit in the amount of \$5,400,000. This grant expires in October 1986. As of June 30, 1985, \$1,475,000 has been drawn down on this grant.

b: Fund balance: The fund balance results from interest earned on industry contributions. This balance will be offset against future industry billings.

c: Office equipment: Office equipment is stated at cost and is depreciated using the straight-line method over its estimated useful life of five years.

d: Accounts payable - research grants: The increase in Accounts Payable - Research grants at June 30, 1985, as compared to the prior year, reflects the expansion in the Institute's research program during fiscal 1985, as well as a concerted effort by financial management to record as of June 30, 1985 all outstanding liabilities for the ongoing research grants.

Note 2: Commitments

a: Leased office space: The Institute currently leases its office space under an agreement expiring in November 1986. Minimum annual rental under this lease will be \$54,132.

b: Research contracts: As of June 30, 1985, a total of \$8,798,000 has been committed by the Institute to fund program-related research contracts, of which \$6,085,000 was expensed through yearend. Subsequently, an additional \$282,000 was committed to further research.

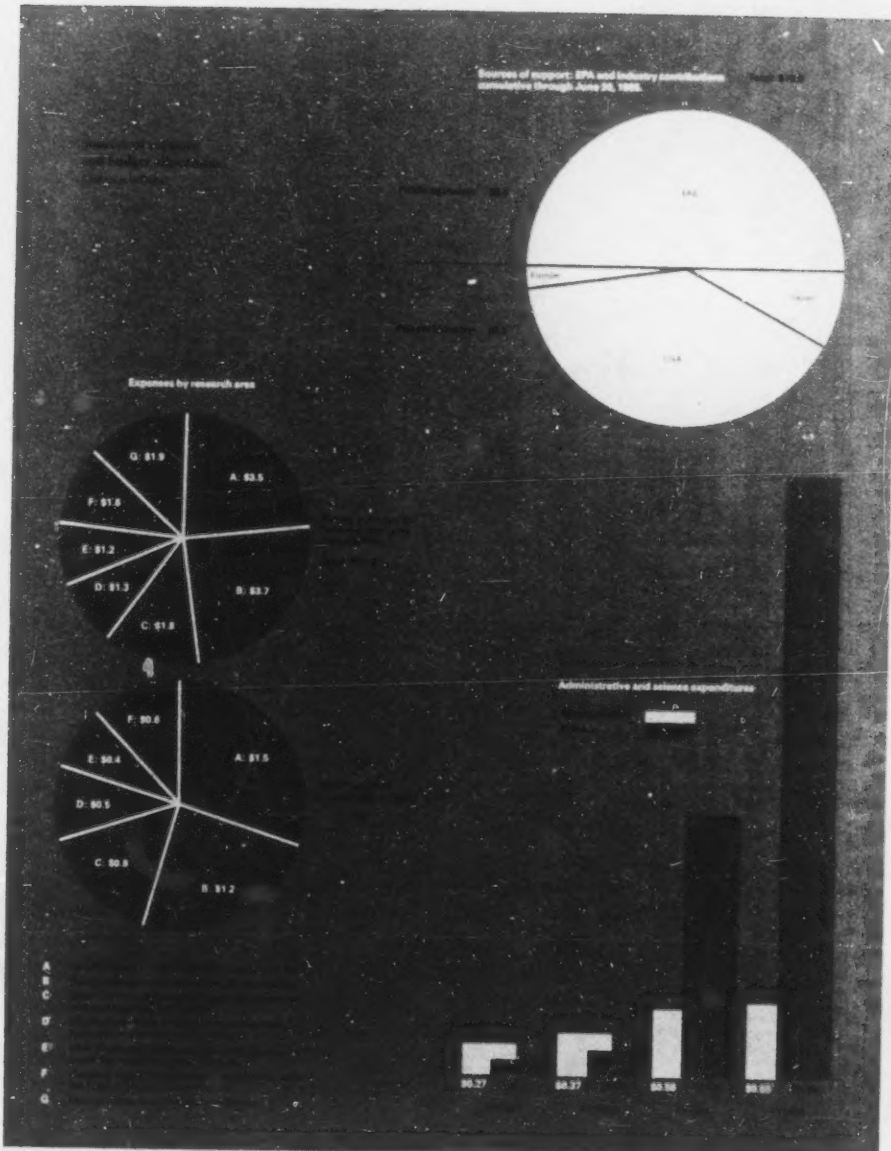
Note 3: Pension plan: The Institute has a defined contribution Pension Plan (the Plan) covering all employees of the Institute. Under the provisions of the Plan, the Institute makes annual contributions equal to 8% of the salary paid to the participant. Pension expense for the periods ending June 30, 1985 and 1984, was \$26,996 and \$13,679, respectively.

Statement of program, general and administrative expenses for the year ended June 30, 1985
Exhibit I

Funded by:	EPA	Industry	Total
Scientific Services:			
Research contracts	\$2,373,718	\$2,324,414	\$4,698,132
Consulting	144,383	144,383	288,766
Salaries and Employee Benefits	216,555	216,555	433,110
Professional Fees	30,041	30,041	60,082
Travel	83,229	127,165	210,394
Administrative Support	25,462	25,462	50,924
Rent	30,734	30,735	61,469
Telephone	9,753	9,753	19,506
Depreciation and Amortization	6,736	9,736	16,472
Miscellaneous	77,696	80,063	157,759
Expenses for the Year Ended June 30, 1985	<u>\$2,998,307</u>	<u>\$2,998,307</u>	<u>\$5,996,614</u>

Statements of actual vs. budgeted EPA grant expenses for the period from the date of incorporation (May 20, 1980) to June 30, 1985
Exhibit II

		Amount Expended:		
	Authorized budget	1985	Through Fiscal 1984	Amount remaining
Grant I				
Personnel	\$ 456,773	\$ 9,440	\$ 447,333	\$ —
Fringe Benefits	52,137	21	52,116	—
Travel	79,657	—	79,657	—
Contractual	2,797,794	1,476,593	1,321,201	—
Other	163,639	—	163,639	—
	<u>\$3,550,000</u>	<u>\$1,486,054</u>	<u>\$2,063,946</u>	<u>\$ —</u>
Grant II				
Personnel	\$ 308,838	\$ 179,358	\$ —	\$ 129,480
Fringe Benefits	60,433	27,736	—	32,697
Travel	83,229	83,229	—	—
Contractual	4,579,103	1,041,508	—	3,537,595
Other	368,397	180,422	—	187,975
	<u>\$5,400,000</u>	<u>\$1,512,253</u>	<u>\$ —</u>	<u>\$3,887,747</u>



Health Effects Institute Consultants and Participants

- Dr. Yves Alarie
University of Pittsburgh
- Dr. Mary Amdur
Massachusetts Institute of Technology
- Dr. Kelley P. Anderson
University of Utah Medical Center
- Dr. Bruce Appel
California Department of Health Services
- Professor Judith C. Aron
Georgetown University Law Center
- Dr. Stephen Ayres
St. Louis University
- Dr. David V. Bates
University of British Columbia
- Dr. Barbara Beck
Harvard School of Public Health
- Ms. Sue Brett
Exxon Corporation
- Dr. Philip Bromberg
University of North Carolina
- Dr. Paul E. Brubaker
P.E. Brubaker and Associates, Inc.
- Dr. Stephen M. Cain
University of Alabama Medical Center
- Dr. Glenn Cass
California Institute of Technology
- Dr. Nicholas P. Cernansky
Drexel University
- Dr. Christopher Chapler
Queen's University
- Dr. Ronald Coburn
University of Pennsylvania
- Dr. Joan Dauby
New York University
- Dr. Jack Dean
Chemical Industry Institute of Technology
- Dr. David K. Deewiler
University of Pennsylvania
- Ms. Maureen Doerr
Doerr Associates, Inc.
- Dr. Donald L. Dungworth
University of C.A. Davis
- Dr. Philip E. Enterline
University of Pittsburgh
- Dr. Barry Fanburg
New England Medical Center
- Dr. Gerald L. Fisher
Battelle Columbus Laboratories
- Ms. Carol Tucker Foreman
Foreman and Company
- Dr. Richard Fox
Children's Hospital Medical Center
- Dr. Robert Frank
The Johns Hopkins University
- Dr. Carl Franzblau
Boston University School of Medicine
- Dr. Bruce Freeman
Duke University
- Dr. Donald E. Gardner
Northrup Services, Inc.
- Dr. Jerry Gillespie
Kansas State University
- Dr. John D. Graham
Carnegie-Mellon University
- Dr. Jack Hackney
Renchen Las Angeles Hospital
- Dr. Donald J. Hanshan
University of Texas
- Dr. Curtis Harper
The University of North Carolina
- Dr. Ronald W. Hart
National Center for Toxicological Research
- Dr. Houn Hassan
North Carolina State University
- Dr. Steven Horvath
University of California
- Dr. Paul Howard
Case Western Reserve University
- Dr. Alan M. Jeffery
Columbia University
- Dr. Yutaka Kikkawa
New York Medical College
- Mr. Richard W. King
Independent Consultant
- Dr. Marvin Kuschner
State University of New York
- Dr. David E. Leith
Harvard Medical School
- Dr. Matthew Levy
Mount Sinai Hospital
- Dr. Morton Lippmann
New York University
- Dr. Robert B. Loffield
University of New Mexico
- Dr. William Lovatance
Rockefeller University
- Dr. Harold N. MacFarland
Independent Consultant
- Dr. Dennis Mahlum
Battelle Pacific Northwest Laboratories
- Dr. Adeb B. Makae
University of Osteopathic Medicine and Health Sciences
- Dr. Robert Mason
National Jewish Hospital
- Dr. Don Massaro
University of Miami
- Dr. James J. McGrath
Texas Tech University
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Research Committee meeting; clockwise from left: Wogan, McClellan, Brain, Stoebner, Tukey, Rock (consultant), Rosenblith, Upton.

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Professor and Chairman, Institute of Environmental Medicine, New York University

Portrait: Charles W. Powers

I believe there is a relationship between goodness and truth. You can't get to goodness without getting the facts right. —Charles W. Powers



At first glance, Charles Powers seems like many other successful American executives. He is forceful, reserved, articulate, even urbane. It is not until he warms to his subject that the realization dawns that he is a mover and a shaker, in every sense of that phrase. He is the kind of man who can change the shape of the world around him.

His academic training was in philosophy — not usually considered the fast-track route to the executive suite. He was awarded a Ph.D. from Yale University; his thesis was on the relationship of philosophical thinking to theological ethics. "But," he hastens to add, "my teaching was largely in the more practical fields; I taught courses on social ethics, on bioethics, on management ethics, and even one on institutional rights, responsibilities, and governance." He became a professor of social ethics at Yale, and ran the graduate program in that subject. In 1974, while on sabbatical, he decided, "I really wanted to test out a lot of things I'd been teaching."

So in 1975 he joined the Cummins Engine Company, a move that he portrays as only logical for an ethics professor. "At Cummins," he explains, "I thought I was going to be in charge of their corporate responsibility area; they started giving me the environmental stuff." As he speaks, his own enthusiasm begins to surface, despite his relatively uninflected speech patterns. He is as steeped in respect and admiration for Cummins as he is in philosophy and ethics:

Cummins had taken a fairly strong position during this part of the environmental movement. As their convictions came to bear on the company's product, Cummins decided to find out if their product belonged in the marketplace, and under what conditions. I wrote some pretty strong policy statements at the time, and one of the things we said was, "No product had an inherent right in the marketplace; if indeed the diesel engine didn't belong there, if the public found it did cause significant threat to health and welfare, then it shouldn't be there."

At this point, a pragmatic streak also begins to glimmer through the conversation; he notes, for example, that Cummins' view of the environmental movement "was not Pollyanna-ish." His continued involvement with environmental affairs while at Cummins ultimately led him to propose, build, and launch the Health Effects Institute, an eminently practical solution to a real-world adversarial situation that others would have dismissed as — precisely — Pollyanna-ish. This remarkable fusion of pragmatism and idealism is Powers' hallmark, a worldview that pervades everything he touches. Listen, for example, to his perspective on the carbon monoxide study.

In August 1983, HEI's second major round of Requests for Applications, recently released, still seemed to take a more "basic science" approach to issues than either side liked. Therefore, when EPA said, "We've got a real problem with the carbon monoxide standard," there was a kind of practicality to the request that let both the industry and the EPA heave a sigh of relief.

For HEI, that was a very important moment for the EPA to say, "We stand behind this organization, and this is our most serious problem at the moment. Carbon monoxide is the one pollutant that automotive sources are the primary contributor toward, and HEI is the group to whom we're going to turn — not just for some basic scientific research but for some quite specific data on the parameter, i.e. angina pain, that we have used as the basis for our previous standards."

That was very unusual for the EPA. Their request on a specific standard came at a moment when the practical relevance of HEI's work was still in question, so to be asked to take that on made the relevance question irrelevant. And it's equally important to realize that, at that same time, HEI had been looking at the CO issue and had made sure that it was not focused only on angina pain; the Research Committee was also looking at whether or not CO caused exacerbation of symptoms of people who had chronic obstructive pulmonary disease, whether or not it had increased the response of people who had sickle-cell anemia, whether or not people who are older, whose cardiovascular systems were older, had adverse response to CO.

The institution, then – in a way which the EPA had not asked us to do – was looking at other possible parameters where people got into trouble with CO. That's the whole pitfall in how we've set standards historically...the regulatory community gets focused on one piece of a possible problem, takes one kind of evidence as a basis for regulation, and rides everything on it.

Powers seems to operate on the belief that, if you've got your facts right, you can always see your way clear to some sort of constructive action, no matter how seemingly intractable the problem. He tells of being cautioned once by Henry Schacht, Cummins' chief executive officer, when a particular project was not unfolding as Powers had hoped, "Chuck, it sounds like your wishes are getting in the way of the search for truth; never forget – facts are friendly." His mode of analysis seems to be first to discover where the log jam is in any particular situation, then to discover what forces are acting to preserve that log jam, and finally, to see what motivations could induce the prevailing forces to change. Pragmatically, he often clearly sees how a profit motive can be used to drive change.

His current effort is Clean Sites, Inc., where he has applied this philosophy to get major firms to help clean up toxic waste dumps – voluntarily and at their own expense. Stated so boldly, it sounds

like an implausible proposition to sell. Yet, once Powers musters his impressive array of facts to point out that the firms will spend less on actual cleanup expenses if they band together and do it voluntarily than they will if forced to do it through governmental action – which would cost them both litigation expenses and clean-up costs – it makes perfect sense. Still and all, he does acknowledge that "Clean Sites was born in much more active controversy than HEI was."

For someone as dedicated to change as Powers, he appreciates that change does not come easily; besides persistence, it takes plain old-fashioned luck, and the right mix of people. "Every single institution that's part of this had to fight back very strong pockets of internal resistance along the way; really true independence is something that is unnatural for institutions to embrace." Perhaps it is that appreciation that also gives him his refreshingly human ability to savor any fruits of change. He speaks of those who have thrown in with HEI with an almost paternal pride: "What's gathered in that institution in terms of talent is no place else in the environmental field; it just doesn't exist."



The Health Effects Institute at a glance

The Health Effects Institute, established in 1980, is a non-profit corporation chartered to study the health effects of motor vehicle exhausts. Each of HEI's research projects has one or more goals; these range from providing information that has direct and immediate policy-formulation relevance, to research that paves the way for developing such information later on. Specifically, the research goals are:

- To identify and quantify human risks from various pollutants;
- To develop methods of toxicologic assessment that can predict health effects in humans;
- To develop sufficient understanding of the mechanisms of toxicity and factors affecting sensitivity and pathogenesis to permit development of methods that would help achieve the two preceding goals.

HEI's annual operating budget is contributed equally by:

- Environmental Protection Agency
- Manufacturers and marketers of motor vehicles in the U.S.

None of these contributors has any control over the conduct or conclusions of HEI studies. The automotive industry's share is contributed by the following firms in proportion to their vehicle and engine sales:

General Motors Corporation
Ford Motor Company
Chrysler Corporation, Inc.
Toyota Motor Company
Nissan Motor Company, Ltd.
Cummins Engine Company
Honda Motor Co., Ltd.
American Motors Corporation, Inc.
Volkswagen of America, Inc.
Mazda Motors of America, Inc.
International Harvester
Caterpillar Tractor Co.
Subaru of America, Inc.
Mack Trucks, Inc.
Volvo of America Corporation
Mercedes-Benz of North America
BMW of North America, Inc.
Isuzu Motors, Ltd.
Mitsubishi Motors Corporation
Saab-Scania of America, Inc.
Renault USA, Inc.
Jaguar Rover Triumph, Inc.
Peugeot Motors of America
Alfa Romeo, Inc.

HEI's budget, in fiscal year 1985, supported 40 research projects at 35 institutions in North America and Europe, in the areas of:

- Health effects of low levels of carbon monoxide;
- Health effects of emissions from diesel vehicles;
- Effects of nitrogen oxides on lung development, and on susceptibility to infection;
- Effects of nitrogen oxides, ozone, and diesel exhausts on susceptible populations;
- Identification of early markers of lung disease related to mobile sources emissions;
- Gauging dose to target tissues actually produced by different types of exposures to pollutants;
- Mechanisms of oxidant injury in the lung.

HEI's funds are controlled, within the limits of its charter, solely by the Board of Directors, consisting of:

- **Archibald Cox**, Chairman: *Carl M. Loeb University Professor (Emeritus), Harvard Law School, former Solicitor General of the United States*
- **William Baker**: *Chairman Emeritus of Bell Laboratories, Chairman of the Board, Rockefeller University*
- **Donald Kennedy**: *President, Stanford University, former Commissioner of Food and Drugs*
- **Charles Powers**: *President, Chon Sitt, Inc., founding Executive Director, HEI*

The Board operates independently, and is responsible for all HEI activities, including a scientific mission carried out by two autonomous committees and their chairmen:

- **Walter Rosenblith**, Health Research Committee: *Institute Professor and former Provost, Massachusetts Institute of Technology*
- **Robert Levy**, Health Review Committee: *Professor of Medicine, Columbia University, former Director, National Heart, Lung, and Blood Institute*

The Board and the Committees are supported in carrying out their day-to-day operations by HEI's administrative and scientific staff, led by Executive Director Thomas P. Grumbly, formerly a partner at the management consulting firm of Temple, Barker, and Sloane, staff director for the Investigations and Oversight Subcommittee on Science and Technology, U.S. House of Representatives, and executive assistant to the Commissioner of the Food and Drug Administration.

Mr. POWERS. The task of developing institutions like this lies in front of us. We think we have some ideas about it, and would be glad to respond to your questions. Thank you for your attention.

Mr. SCHEUER. Thank you very much, Dr. Powers.

Dr. Baker.

STATEMENT OF DR. WILLIAM O. BAKER, PRESIDENT EMERITUS OF BELL LABORATORIES AND MEMBER, BOARD OF DIRECTORS, HEALTH EFFECTS INSTITUTE

Dr. BAKER. Thank you, Mr. Chairman. I really support strongly the conclusions my colleagues have said.

I might only add that the industry involved in the HEI has been uniformly forthcoming in respect to the availability of its own research and development studies, and one is reminded by your comments about the problems of the chemical industry that here, in the question of engine emissions, we have found very complete access to these once-proprietary studies and analyses.

Mr. SCHEUER. I didn't quite get that. Who has complete access to these once-proprietary—

Dr. BAKER. HEI.

Mr. SCHEUER. HEI does?

Dr. BAKER. Yes.

Mr. SCHEUER. Well, you're way ahead of EPA. And maybe that's one of the great advantages—

Dr. BAKER. That is a heartening conclusion, Mr. Chairman, and we aspire to involve that particular quality of the HEI, as my associates have reported.

Mr. SCHEUER. That's at once a little discomfoting, that EPA can't get the information; after all, they're fighting for the health and safety of our country—as well as a private, nonprofit group. But maybe that simply goes to highlight that under our current system of legal and institutional arrangements, this kind of an ad hoc mechanism is extremely well conceived and, on a very pragmatic basis, is better qualified than any other institution around to get that information early, the scientific information, and get it where it ought to be, to the people who are best qualified to produce some answers and get those answers into the stream of science, commentary, and into the manufacturing process, ultimately.

We're absolutely delighted that you are here, Dr. Baker, that you were able to rearrange your schedule or whatever. We couldn't be more pleased. You are the only industry rep here. Perhaps as our first research project we ought to figure out a way of cloning you so that all these affected corporations can have a Dr. Baker on their board. What do you think about that, Professor? [Laughter.]

OK. Let me ask you a question. As you begin to put together scientific projects—Claudine?

I am going to catch this rollcall vote, and I am going to turn this chair over to our distinguished ranking minority member so that we won't lose any precious time for you because we have to vacate this room a minute or two before 1 o'clock. So I'll be back in about 12 or 13 minutes, and I now turn the chair over to Madam Schneider.

Miss SCHNEIDER [acting chair]. Thank you, Mr. Chairman.

I welcome all of the members of the panel—Dr. Kennedy, nice to see you again—and other members. I regret that I had to cover another appointment so I couldn't hear the full testimony, but I do have a number of questions that I'd like to run through quickly.

First of all, Dr. Powers, could you elaborate about Clean Sites, share with my colleague and others exactly what Clean Sites does?

Mr. POWERS. Clean Sites is not an organization primarily devoted to the development of facts related to hazardous waste sites. It is devoted to trying to promote settlements between the Government and responsible parties at sites. That does involve a very major technical and scientific enterprise as well, and we have a Technical Advisory Board at Clean Sites which in many ways is reminiscent of the kind of a review committee that you heard Dr. Kennedy describe.

Our job is to bring the parties together, help create settlements, make sure that the technical and scientific work being proposed for a cleanup is going to be adequate and that the health and safety prerequisites are there in the cleanup process. And when the parties so desire, we will help them organize the project management of the cleanup, and we're making enormous progress on that at the moment.

Miss SCHNEIDER. And what are some of the industries that are involved in that effort?

Mr. POWERS. Well, you'll find a very large number of industries forming our contributing base.

Miss SCHNEIDER. Monsanto, Du Pont?

Mr. POWERS. Well, the chemical industry, the steel industry, the pharmaceutical industry, the electrical manufacturing industry, the petroleum industry; it's really quite diverse. And I might go on to point out that we have participation in work that we're doing at settlements involved from about 15 industrial sectors. So we're working with 1,200 responsible parties involving companies from every industrial sector who are actually involved in the settlement process.

Miss SCHNEIDER. Well, the reason I am asking that question is because, obviously, much of the effort there is through compromise, cooperation, and a congealing of various interests to solve the problem. One of the things that we're trying to do in this new age is to move from the confrontational approach to a cooperative approach, and I think that the Health Effects Institute is a reflection of what can be done in the research end of things.

I am curious to know if there are some other priority areas. You had mentioned indoor air; you probably did your homework and noted that I was more likely than not going to be here this morning, so I don't know if you're playing favorites, but are there some other areas of interest that you feel would be high priority areas for investment?

Mr. POWERS. I think we're interested in distinguishing between those areas where the primary questions are related to the development of scientific facts, which are those which are most clearly related to what we're talking about this morning, and those which deal with other kinds of industry/Government cooperation. I think that is apt, and what we'd like to focus on primarily this morning is places where the development of fact for regulatory use could be

most actively pursued. And I suggested indoor air pollution and other toxic air emissions. I know that both Dr. Kennedy and Dr. Baker have a lot of other ideas, so I should let them talk.

Miss SCHNEIDER. All right.

Dr. Kennedy.

Dr. KENNEDY. I would just mention that, in the area of food additives regulation, there is clearly an opportunity. Although industry is required under law to provide evidence about the safety of new food additives, there is a serious questions how we deal with the ones that were already out there when the food safety laws were amended, and that has presented a number of difficulties in the past. I think the model might work there. I think it might very well work with pesticide evaluation.

Miss SCHNEIDER. OK.

Dr. Baker, did you want to add anything?

Dr. BAKER. Well, thank you. I think that is a very good example. We see opportunities in other fields which may demand some regulatory attention in the future, such as biotechnology as it is emerging; it would be a similar tactic.

Miss SCHNEIDER. Mr. Cox, you look like you're anxious to say something. Is that so, or shall I move on to the next question?

Mr. Cox. No, I think they've given a fair sample of examples. I think there are several sort of prerequisites; I think for the model to work, you have to have a segment of industry that can be marked off in terms of problems, and get them involved. And then you have Government on the other side. And where people have started with an antagonistic relationship, then it seems to me—perhaps I spent too many years being the man in the middle in labor-management relations—but it seems to me that it's very important to have some independent people who keep focusing on their mutual responsibility and, where research is involved, can undertake to do it in a way that everyone must acknowledge is fair and independent.

Miss SCHNEIDER. Right.

Well, let me recognize my colleague because we, too, have to run over for a vote very quickly. The 10-minute signal has been given.

I would like to say, though, that as a member of the board of the Business Higher Education Forum, we have our conference coming up in April. I'm very interested, since I have to do one of the speeches, to come up with some innovative ideas where this kind of partnership might be useful. And so I am receptive to any input that you gentlemen might have prior to that. Unfortunately, I don't want to take the time away from my colleague for you to respond to that right now; but if we have any time after he speaks, I'll be happy to hear from you.

Mr. RITTER. I think we both have to go and vote.

I guess my question is a broader one, and perhaps you could think about it while we're voting. But I'd like your input on your feelings of the state of the art of health effects research today and how that works within the regulatory process and whether or not it does work within the regulatory process.

And I think at this point that we should go and vote.

Miss SCHNEIDER. Well, regrettably, we will have to adjourn until the chairman returns, which should be momentarily. So I thank you gentlemen for your input. We'll be right back.

[Recess.]

Mr. SCHEUER [resuming chair]. OK; we'll resume now.

Dr. Kennedy, I understand that you were on the verge of answering a question when we suspended.

Mr. KENNEDY. Mr. Chairman, Congressman Ritter had asked for an evaluation of the state of the science that underlies health effects research at the moment. I'm not sure any two scientists would give you exactly the same evaluation.

I think our impression is that the most serious problem, as it is with all toxic effects research, is that there's a kind of mismatch between how much hazardous this or that we can identify—the science of analytical chemistry has been wonderfully progressive—and how much—how carefully we can assess risks, because there are different difficulties with toxicology and epidemiology, the two sciences that we employ to identify risk. Epidemiology is wonderful but it requires large samples and long times, often; it's expensive. We're very fortunate when we can use it, but often it lacks the sensitivity required for us to measure risk at the levels that we're interested in measuring it for regulatory purposes. Toxicology hasn't come as far as we would like; it's time consuming and expensive itself. And, of course, extrapolating the risk from experimental animals to humans, as you and I both know from other days, presents all kinds of problems.

We hope very much that the Scientific Program of the Health Effects Institute will broaden the base of good science from which we can work. That's why we're devoted to the area of methods development and some other longer range things, as well as programs aimed at problems that contribute to immediate regulatory challenges. I would think, for example, that the development of recombinant DNA, DNA adduct techniques of other in vitro methods for evaluating risk is the most promising area, but still some distance away from immediate regulatory utility.

Mr. SCHEUER. Well, we are all enormously impressed with the work that you are doing. I just can't imagine a more fruitful field for the application of your manifold talents than exactly and precisely what you're doing now. And perhaps the benefit of it is that it's an industry/science collaboration, with you playing a role of ringmaster and general leadership role, a catalytic role; and perhaps the genius of your idea is that it doesn't involve Government at any level.

Can you think of any role that Congress—we're all so eager to move this thing forward, and perhaps advance your area of concern to other fields like the chemical field, like the smokestack industries. Is there any way that Congress could advance it, or is the genius of the idea the simple fact that no Government presence is involved at all? I mean, from that point of view, it's pure and undefiled. Can you see any congressional role? Is there anything we can do to encourage this—

Mr. Cox. I think there are three things that are relevant to say in answer to that question, Mr. Chairman.

One, of course, to help us assure our continuance in terms of funding, so we're there. I don't mean to be——

Mr. SCHEUER. Do you have Government funding now?

Mr. Cox. Well, we're funded half by Government and half by industry.

Mr. SCHEUER. Oh, half by EPA. I get it. Half by EPA. That's right.

Mr. Cox. So given all the conditions that exist today, it's very important that we continue to get the EPA funding. Needless to say, you can help on that.

Mr. SCHEUER. Is that funding earmarked in EPA? Is that a line item in the budget?

Mr. Cox. It is not presently a line item.

Mr. SCHEUER. Under what category of funding does it come?

Mr. Cox. I think it's under their research.

Mr. SCHEUER. OK. Please proceed.

Mr. Cox. Second, your very interest and expressions of interest in this kind of thing—expressed both to Government agencies and to industry—would be very important, that HEI stands as a model.

Third—this is sort of a follow-on, too—third, I think accomplishing setting up something like HEI is, in part, a matter of timing. The industry has got to be at the point of wondering about its status——

Mr. SCHEUER. Wondering about——

Mr. Cox. Wondering about its status, wondering about what the price will be if it doesn't begin to think of cooperating. And, you know, you've used the word "catalyst"; quite right. You get a certain set of tensions, fears, hopes, then some energetic people from outside who have no axes to grind can come in and serve as the catalyst. And I think your sense of creating that sort of mix——

Mr. SCHEUER. Well, I'm not creating it. I wish I had been the creator, but you created it and I'm simply hoping that we will extend the area that you have covered to these other fields.

Mr. Cox. Well, but I think you could make people think a second time, third time, fourth time about whether they aren't in that situation where they shouldn't be thinking about the kind of quite fundamental reexamination that the automobile industry engaged in. There was a real decision back there that led to the establishment of HEI.

Mr. SCHEUER. And I suppose that the problems and the tensions and the controversy accumulated and accumulated and accumulated and at some point in time you hit a critical mass——

Mr. Cox. That's right.

Mr. SCHEUER [continuing]. Where industry finally said, among their colleagues in the elite leadership group, we've just got to do something different. We can't continue down this road.

Mr. Cox. And something similar on the Government's side, although it's not quite as great a problem.

Mr. SCHEUER. Yes.

Dr. KENNEDY. I do want to emphasize that EPA saw and understood that problem, too, and that the leadership and scientific working staff in EPA have been very important in making this go as well, and superbly cooperative.

Mr. POWERS. Mr. Chairman, I think that the founding press conference, at which HEI was announced, articulates this about as well, and I would suggest that we should add that to the record, because the presence at that point of the Administrator of the Environmental Protection Agency and the leadership of the automotive industry and their explanation of how they got there is very key.

[Material referred to follows:]

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1 THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4 PRESS CONFERENCE

5 HEALTH EFFECTS INSTITUTE

7 National Academy of Science Auditorium
2101 Constitution Avenue, N.W.,
8 Washington, D.C.

9 Friday,
10 December 12, 1980
10:00 a.m.

14 Participants

15 Archibald Cox, Carl M. Loeb University Professor
16 Harvard Law School

17 Douglas M. Costle, Administrator
18 Environmental Protection Agency

19 Thomas A. Murphy, Chairman of the Board and
Chief Executive Officer,
20 General Motors Corporation

21 Dr. William O. Baker, Chairman of the Board
of Rockefeller University

22 Henry B. Schacht, Chairman and Chief
Executive Officer
23 Cummins Engine Company

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Participants (Cont.)

Alfred W. Pelletier, Chairman of the Board
and President
Mack Trucks, Inc.

Roger Smith, Chairman-elect,
General Motors Corporation

William Baker, Chairman of the Board,
Rockefeller University

Donald Kennedy, President,
Stanford

Dale Compton, Vice President,
Research; Ford Motor Company

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P R O C E E D I N G S

MR. COX: Ladies and gentlemen, we asked you to join us here this morning so that Douglas Costle, the Administrator of the Environmental Protection Agency, and I and the representatives of the industry who are present might announce the formation of a new and independent Health Effects Institute.

We believe, indeed we're confident, that the establishment of the Institute is a major breakthrough in cooperation between a regulatory agency and the industry and the independent sector of the public in providing a mechanism to produce the information which ultimately is important in protecting the public health.

The function of the Institute will be to conduct, by contract or grant, and to evaluate the tests and research necessary to determine the health effects of automotive emissions. This knowledge is required in the implementation of the Clean Air Act and, more generally, in the protection of the public health.

The Institute will take the scientific testing and research needed to ascertain health effects out of the adversarial context in which it might otherwise be performed. And thus, it will supply both EPA and the industry and the Congress and the public with the best common base that independent scientific investigation can provide for determining

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1 on the basis of those facts what regulatory consequences
2 should follow.

3 The Institute, as I said, is being established
4 through the cooperation of members of the industry who are
5 here, the companies represented here, and the Environmental
6 Protection Agency.

7 It will, however, be an independent organization
8 with its own governing board. It will be funded by EPA and
9 the automotive industry with the automotive companies sharing
10 according to an agreed formula. I will fill in a little
11 more substance later.

12 But let me first introduce those who are present.
13 And later, I will ask some of them to speak.

14 On my right, as you will recognize him, is Douglas
15 Costle, the Administrator of EPA. And on my left is
16 Dr. William Baker, recently retired Chairman of Bell Labora-
17 tories and the Chairman of the Board of Rockefeller University.
18 Mr. Baker, along with Donald Kennedy, the President of
19 Stanford, and I, myself, will be the three directors of the
20 Institute.

21 Also here with us, I'm happy to say, is Mr. Thomas
22 Murphy Chairman and Chief Executive Office of General
23 Motors Corporation. And with him is Mr. Roger Smith who will
24 be his successor. Next to Dr. Baker is Mr. Henry Schacht,
25 Chairman and Chief Executive Officer of Cummins Engine.

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1 And also present is Mr. Alfred Pelletier, the
2 Chairman and President of Mack Trucks. Next, Mr. Dale
3 Compton of Ford. And you have a list of the other companies
4 and their representatives who are present.

5 Let me take just a few minutes to describe the
6 Institute, itself. One starts with the proposition, which
7 is not subject to dispute, that uncertainty about the health
8 effects of emissions and effluents is a major factor confound-
9 ing environmental protection in this country.

10 The problem is that there's too much that we just
11 don't know. Our knowledge is in proving both in terms of
12 data and methodology, but both leave much to be desired.
13 Without some form of joint endeavor, testing and research
14 would almost inevitably, and all too often, be conducted by
15 interested parties in adversarial contexts.

16 If the search for facts, scientific facts, is part
17 of an effort to protect interests or to support preconceived
18 views, then the result is bound to be public confusion, regu-
19 latory delay or, perhaps, over-reaction. It also would be
20 wasteful in a period when our economy needs to become more
21 productive and when the scientific resources, especially
22 personnel, are scarce, we need to make the best possible
23 use of them too.

24 So, as I say, the functioning of the Institute will
25 be to take the testing and research into the health effects

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1 of automotive emissions out of the adversarial context and
2 to provide both the regulators and the regulated and the public
3 with the best information that science can provide.

4 The Institute will be independent, and at the same
5 time it will be an instance of cooperation because, as we
6 explain at more length in my statement, the program of research
7 priorities will be the result of information, recommendations
8 from both members of the industry and EPA.

9 The top of the Institute will be the board of
10 directors. The bulk of the scientific research will be
11 planned and, in that sense, directed by what we call a health
12 research committee where the aim is to attract to it the top
13 men in the scientific community in each of the disciplines
14 that is of significant importance in ascertaining the health
15 effects of emissions.

16 That group, provided with the necessary staff, will
17 lay out a program consulting the public and EPA and the
18 industry, and then most of the work will be done under
19 contracts or grants with those laboratories, universities and
20 others that have facilities for doing that kind of research
21 and testing.

22 After the research is done and the findings are
23 reported, then, in order to ensure the highest possible
24 scientific quality before publication it will be submitted to
25 another committee, the health review committee made up of

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1 scientists, who will check it for the adequacy of the protocols
2 to determine whether the data collected supports the con-
3 clusion.

4 And will put or withhold in the matter of the
5 Institute purely on the basis of the scientific quality,
6 research quality, of the work that has been done. That data,
7 made available to all, should then be of use in the regula-
8 tory process. And the Institute won't be concerned with the
9 regulatory consequences to be drawn from the data.

10 As I say, the aim is to take the establishment of
11 the data out of the area of adversarial presentation. And
12 the adversarial presentations, undoubtedly, will then be
13 made on the basis of what the scientists have determined.

14 I would simply add briefly at the end a word or
15 two to describe why I think the inauguration of the Institute
16 is a very significant accomplishment. There's been a sort
17 of a vacuum. As a lawyer, I know that the adversarial process
18 serves many what I believe to be useful purposes.

19 But one of them isn't doing good testing and
20 research. Testing and research ought to be kept free of
21 any taint or suspicion of taint of financial interests or
22 preconceived policy judgment. On the other hand, we shouldn't
23 paper over the fact that there may be subsequent separate
24 differences of opinion as to what regulatory conclusions
25 should be followed.

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1 We would like to think that the Health Effects
2 Institute may provide an example of cooperation among those
3 involved in protecting the environment that might be followed
4 in other areas. It's quite plain, I think, that getting this
5 far in setting the Institute up is a tribute to EPA and to
6 the members and executives in the industry.

7 I think the importance that they and we attribute
8 to the undertaking is indicated by the men who have come to
9 join in this announcement today.

10 Doug, would you like to add?

11 MR. COSTLE: Thank you, Professor Cox.

12 I am extremely pleased that we're able to announce
13 today the formation of the Institute. And I am particularly
14 pleased that we've been able to persuade three such dis-
15 tinguished gentlemen to serve as the board of directors and
16 incorporators as Dr. Baker, Professor Cox and Don Kennedy.

17 I believe that the Institute has enormous potential
18 to provide significant benefits to the public. While regu-
19 latory agencies, as Professor Cox has said, in affected
20 industries are frequently cast in adversarial roles, far
21 too often the adversarial roles are carried over to the
22 scientific underpinnings of the regulatory programs.

23 When that happens, that can and does, in fact, erode
24 public confidence in the entire process. In addition, the
25 conduct of health effects research in this adversarial

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1 environment is inefficient, sometimes inequitable, and almost
2 certainly excessively slow and, in general, a poor use of
3 scarce facilities and competence.

4 I have supported the concept of this Institute with
5 the expectation that it will help resolve many of these prob-
6 lems and result in a better health effects data base for all
7 of us to use as the basis for formulating public policy.

8 EPA fully supports the charter, the operating
9 procedures and the leadership of the emerging Institute. We
10 have created, I believe, a new kind of institution whose
11 organizational format will give it both the competence and
12 independence so essential for disciplined and credible scien-
13 tific inquiry.

14 My expectation is that EPA and the Institute, while
15 each retains independence, will cooperate very very closely
16 with frequent consultation in the development of our respective
17 health effects research programs. And EPA in particular will
18 cooperate in advising and recommending priorities and protocols
19 for the Institute's research activities.

20 EPA shall maintain a health effects research
21 program capability of its own for the development of experi-
22 mental protocols, for the conduct of more basic health effects
23 research and for the periodic validation of research results
24 obtained elsewhere.

25 Duplicative research, except where scientifically

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1 warranted, should be eliminated. I expect that health effects
2 research performed by the Institute will be an integral part
3 of EPA's overall research planning and that the Agency will
4 continue to provide financial support to the Institute.

5 Because of the caliber of people who have already
6 agreed to participate in this undertaking and the expectation
7 I have for the caliber of scientists that they will draw
8 to it, I would expect to be able to place the highest level of
9 confidence in health research conducted by the Institute.

10 The very purpose of the Institute is to enable all
11 of us to move away from both the reality and the appearance of
12 adversarial research and toward the products of research that
13 we and the American people have confidence in. We anticipate
14 that the Institute will become, if all goes well, the major
15 source of studies on the health effects of motor vehicle emis-
16 sions in the country and a key to improving EPA's capacity to
17 tie its regulatory action to sound health effects findings.

18 Finally, it is important that EPA continue to
19 administer with an even hand its Clean Air Act authority to
20 require health effects testing. All firms subject to that
21 authority, both domestic and foreign, should be expected to
22 carry their fair share of the testing burden.

23 And we would fully expect, however, the Institute
24 to become the primary mechanism through which participating
25 motor vehicle and engine manufacturers can discharge their

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1 health testing responsibilities under the Act.

2 A personal note, we've worked, all of us here, to-
3 gether for nearly two years to bring this Institute into
4 being. And I would just like to say that I personally feel
5 very very good about the fact that we've arrived today at
6 this point.

7 And I think we've launched something that will serve
8 us all well in the future.

9 MR. COX: I would simply add that our being here
10 today is a tribute to Doug Costle's creativity and construc-
11 tive imagination. I'm awfully glad we can do it while
12 he's here.

13 It's not possible to call on each of the companies
14 and their executives who are present, but I have asked a few
15 representatives of the industry to say a few words. The first
16 of them is Mr. Thomas A. Murphy of General Motors who I
17 introduced to you earlier as the Chairman and Chief Executive
18 Officer.

19 Mr. Murphy, we're glad to have you here in support
20 of your company. Would you like to say something?

21 MR. MURPHY: Thank you very much, Mr. Cox, and
22 thank you, Doug, for your being here today.

23 I am pleased and very proud to be here at the
24 launching of this very significant milestone, in my judgment,
25 in constructive cooperation between industry, government and

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1 with the involvement of some dedicated public members of this
2 Health Effects Institute because without the dedication and
3 without the willingness of the public members to participate
4 in this effort, it just simply wouldn't be, in my judgment,
5 the milestone that it is.

6 And that gives the promise of establishing a very
7 important instrument for addressing one of our significant
8 problems in our country today. By getting these dedicated
9 people, and we are indebted to you, Mr. Cox, Mr. Baker and
10 to Don Kennedy as well, that a willingness to take on an
11 important responsibility to help establish the independence
12 and the credibility of this particular effort.

13 I can't over-emphasize the importance of both of
14 those things, the independence and the credibility. The ~~the~~
15 problem we're all aware of and we all want to have a good
16 quality in the air. And Doug, you, in your capacity as the
17 Administrator of EPA, have certainly done an outstanding
18 job.

19 We respect you for the job you have done during
20 the period of time that you've been in Washington and, of
21 course, before you came to Washington you were already
22 involved in this effort. And without your willingness to
23 participate cooperatively in this effort, why, obviously it
24 wouldn't have happened.

25 But I guess I have to also say and express my deep

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1 appreciation for Henry Schacht and the way he went at this.
2 When he first came up with this concept, and I guess it must
3 be three years ago, if I recall, I thought, what a wonderful
4 idea but it probably won't go anywhere because some of the
5 best ideas are not always embraced as fully as they could
6 and should.

7 But because of Henry's dedication, because of his
8 drive and determination and because of the response that Doug
9 and the people at the EPA gave the concept, we are here
10 today and with the willingness of the public members,
11 Messrs. Cox, Baker and Kennedy, we have embarked on this pro-
12 gram that I think is going to be one of the more enlightened
13 efforts in the history of our government in this particular
14 area.

15 Now, it isn't going to happen automatically. Ob-
16 viously, it's going to take a lot of time and effort and
17 dedication on the part of the people involved. But I can
18 assure you on the part of members of the industry, and speaking
19 for my own company in particular, we are dedicated to getting
20 this done.

21 We are all interested in the quality of the air.
22 Unfortunately, you know, even with all the money, all the
23 effort that's gone into that particular program up to the
24 present time, we still have only a, really, fragmentary
25 knowledge and understanding of our atmosphere, the impact of

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1 man-made pollution on it, especially the levels at which
2 health effects occur from various pollutants.

3 And until we fill in more of those voids in our
4 knowledge we can never be sure that our efforts are truly
5 protecting public health and welfare. So it is an effort
6 that does require, I think, important inputs from industry,
7 from government and importantly from the public sector.

8 And that's why we're so pleased to have the public
9 members involved and the quality of the members we have. If
10 You went into the community and tried to pick the absolute
11 best I think that's what we have in this particular effort.

12 Doug, we appreciate the fact that you and EPA have
13 gone into this thing as openly and with a willingness the
14 way you have. Your financial support and commitment for the
15 future speaks for itself and the importance that you put
16 on this effort.

17 And we're just proud to be here and to be able to
18 be part of this effort. And I thank you very much, Mr. Cox.

19 MR. COX: Thank you.

20 I introduced Dr. Baker to you earlier. It does
21 run through my mind that if I were to read the list of all
22 his present activities, not to mention his accomplishments
23 in the past, it would keep you here all morning. We were
24 exceedingly fortunate in eliciting his help and support during
25 the period in which we were forming the structure of the

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1 Institute and will be engaged in beginning to put it into
2 operation.

3 The future will have to determine how much longer
4 he can stay with us. But we're awfully lucky in having you
5 now, Bill. And we hope you will stay. And would you be good
6 enough to say a few words?

7 MR. BAKER: Thank you, Professor Cox.

8 As you and others have indicated, we believe, from
9 the scientific and technical base of this program, that new
10 resources and new ways of having science and technology serve
11 the public interest will be created. We think that the EPA,
12 led by its Administrator, Mr. Costle, and his staff, have
13 joined with industry, as Mr. Murphy and his associates have
14 already indicated, in ways that will permit the knowledge of
15 the environment of the organic effects of emissions from
16 engines to be understood and to be specified in ways that
17 we have not been able to do before.

18 Our presence in this building, which represents
19 the national scientific and technical community, is properly
20 symbolic of the resources which we believe the Health Effects
21 Institute can call on.

22 We find that this is a time in the development of
23 the health sciences and technologies which is particularly
24 appropriate for the visions which our Chairman and Administra-
25 tor Costle and Mr. Murphy have already have already outlined.

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1 That is because we are now at a time in bio-medicine
2 when the specific influence of molecules, things which have
3 formed generally the basis of toxicology, can begin to be
4 understood in their systemic effects on the whole organism
5 rather than in some very isolated behavior.

6 And it is the intention of the Health Effects
7 Institute, through the committees that Archie Cox has described,
8 to call on the very best capabilities of our national com-
9 munity and universities and other institutions and, of course,
10 in close cooperation with government and industry laboratories
11 and experts.

12 This is sure to result in a knowledge base which will
13 then be related to a data base which can be provided for
14 the decisions which others may make. But I cite the dual
15 scientific and engineering function of the Health Effects
16 Institute because that, too, is a new and exciting feature of
17 this unprecedented joint venture between our public and
18 private resources.

19 That means, in this combined effort, that we shall
20 have the modern techniques of systems analysis, of data
21 verification, of quality control for protocols and the things
22 which have emerged in recent years to support the strength
23 of findings about health, about large populations, about com-
24 plex systems like the environment, to support the data base
25 that can be derived and, of course, to base those data on the

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1 very best scientific and technical experiments and research
2 capabilities.

3 So that we do believe, Mr. Chairman, that this is
4 going to be a new stage of marshaling our national resources
5 for both research and a very special kind of systems engineer-
6 ing.

7 MR. COX: Thank you.

8 Henry Schacht of Cummins Engine played a very im-
9 portant, critical, almost, role in bringing together the
10 various elements that are concerned with the Health Effects
11 Institute and in contributing ideas concerning its structure,
12 function and organization.

13 And so I would like both to note that and ask him
14 if he would say a few words.

15 MR. SCHACHT: Thank you very much.

16 I think most of the things have been said. The
17 Health Effects Institute is a quest for truth to the benefit
18 of all of us, the general public who live and breathe the
19 environment with which this planet is blessed. I think it's
20 a simple fact that it brings together people who care about
21 that so much whether they be administrators, whether they
22 be industry people or whether they be the general public.

23 And that's what we're about. And the simple ele-
24 ment -- the essential element here is it's a quest for truth
25 to which all of us are dedicated. And I think the important

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1 thing is that we have decided amongst ourselves that that is
2 the only thing that counts.

3 And if we know clearly what it is that is causing
4 problems, then we are, in our combined roles, dedicated, each
5 in our own way, of doing something about it. That's not new.
6 What is new here is a mechanism whereby that can be pursued
7 in an efficient and in an expeditious fashion.

8 And I think I need to add my thanks, on behalf of
9 this industry, to Doug and his associates, David and Mike who
10 are not here who spent so much time on this, to the three
11 incorporators who are busy men, imminent in their own right
12 and their staff Rich and Chuck who have been with us from
13 the beginning who spent so much time simply because they be-
14 cause they believed this was important.

15 I would also like to thank the many staffs of the
16 member companies who spent long hours on this. The MBNA who
17 acted as a catalyst at very important times when we got
18 bogged down, and their associates, Jim and Paul, who stuck
19 with us.

20 The EMA who worked hard on this. And, of course,
21 the Importers Association. And most of all, I guess, to Doug
22 and Tom who are the respective leaders. Tom, of the largest
23 industry in our industry, and Doug of our public body who
24 is entrusted with these responsibilities because their
25 guidance and wisdom was important.

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1 Thank you both.

2 MR. COX: On my right, part of the way down, is
3 Mr. Alfred Pelletier, the Chairman and Chief Executive and
4 President of Mack Truck. Mr. Pelletier, we would appreciate
5 a few words from you.

6 MR. PELLETIER: Well, thank you, Mr. Cox.

7 I think, as Henry said, almost everything has been
8 said. For an industry like ours, Mack, who only makes one
9 product, a heavy-duty diesel truck, the information that's
10 going to come out of the studies of the Health Effects
11 Institute are most important to a company like ours.

12 In other words, without the information that we think
13 will be sorted out through the Institute, a company like ours
14 who only makes a diesel engine could be legislated right out
15 of business in years to come.

16 So I think without this adversary approach with
17 government, with industry and the public working together,
18 I think we really have a great thing going here. And we're
19 looking to support it financially, technically and with all
20 the manpower that we can afford.

21 Thank you very much.

22 MR. COX: Thank you.

23 I would like to have time to recognize the execu-
24 tives of the other companies who are here. But I do emphasize
25 that you have a list of them. And, perhaps, they will forgive

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1 my discourtesy if I recognize them collectively and simply
2 call attention to the list.

3 Before throwing the floor open to questions, I
4 do think that all of us at the table should acknowledge the
5 importance of the work done by Charles W. Powers who is now
6 associated with Temple, Barker & Sloan Associates, a management
7 consultant; Richard Cooper, a lawyer here in Washington;
8 and Dr. Richard Bates who has served as our chief scientific
9 advisor. When I say "our," I'm thinking of the three directors
10 of the Institute.

11 Also two members of Mr. Costle's staff particularly,
12 David Hawkins and Michael Walsh of EPA who have put in long
13 hours and contributed ideas and effort and cooperation to
14 the undertaking.

15 Well, that presents, when supplemented by the kit,
16 the basic facts. And I'm sure those at the table with me
17 would be happy to answer any questions concerning the Health
18 Effects Institute and the general outlines of the proposal.

19 QUESTION: Mr. Costle, does EPA's participation in
20 the Institute indicate a belief that the chartered Oil
21 Emissions Standard may be based on unsound scientific re-
22 search and, therefore, may be unduly stringent?

23 MR. COSTLE: No. I think the most accurate state-
24 ment is one, I believe in fact, Tom Murphy made and that is
25 certainly also Professor Cox made, that in spite of all the

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1 research that has been done in our understanding of atmospheric
2 chemistry and the subtlety of these problems it's still very
3 fragmentary.

4 Nonetheless, the Congress has passed statutes which
5 require us to take regulatory action, usually under stricture
6 of specific timetables. And we often have to act on the
7 basis of what knowledge we have.

8 In the area of health effects has the fragmentary
9 nature of what we know is even more acute. And I think what
10 we've been searching for here is a mechanism by which we can
11 efficiently coordinate the use of both private and public
12 resources to fill in that data base.

13 And there is much we don't know that we need to do
14 research on. And I think our concern has been that we not
15 be going off in a hundred directions at once that there be
16 unnecessary duplications of scientific research and that we
17 somehow avoid the business of doing defensive research, both
18 the government or the industry.

19 And because of the nature of rulemaking and adminis-
20 trative law, we are often put in an adversarial kind of
21 typesetting. But when it comes to scientific data, we really
22 ought to try to start, I remember as Hank Schacht put it
23 to me three years ago, we ought to try to start with a friendly
24 set of facts.

25 We may disagree about what we should do with the

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1 facts but it's just imperative we start with a friendly set
2 of facts.

3 QUESTION: The idea of joint government and industry
4 in this project while -- has been -- by an indecision on when
5 timing -- if, after six months of the researching project
6 finds adverse health effects -- conversely, if the government,
7 if you find no -- health effects, industry might be very
8 anxious to publish it immediately.

9 And the government might want to say let's go
10 on -- preliminarily.

11 (Question is largely inaudible due to questioner
12 not being at microphone.)

13 Can you tell us what guidelines might govern the
14 decisions of the Health Review Board if after a specific
15 period of time you do or do not find adverse health effects
16 and what position --

17 MR. COX: I think the major difference between this
18 and all previous attempts at cooperation between industry
19 and government in this general area that I'm familiar with
20 is that the decisions affecting such questions as timing
21 and publication will all be made by independent bodies.

22 The directors will be independent and not, in any
23 sense, dependent on the consent or approval of either EPA or
24 the industry in terms of the decisions they make about timing
25 and release. And I would expect that the ultimate consideration

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1 governing questions of timing would be -- perhaps I misused
2 the word -- but would be scientific. That they would be
3 what a scholar, a researcher, would determine what's necessary.

4 If he feels from that point of view the product that
5 has been turned into the Health Review Board, ultimately the
6 directors, is inadequate, then he will hold it up regardless
7 of who it helps or hurts. If it's scientifically validated,
8 then it should be published and the information be made
9 available to everybody just as fast as it has been validated.

10 QUESTION: But scientists frequently --

11 (Question is inaudible due to questioner not being
12 at the microphone.)

13 MR. COX: Well, all they could do is make the
14 best scientific judgment they can from an independent scien-
15 tific point of view. That's the way it will be made. It won't
16 be made in terms of whose ox is bought.

17 QUESTION: Mr. Cox, this report may not be out
18 in -- time for revision of the Clean Air Act next year. Is
19 that correct? This may not influence the consideration of
20 that bill next year?

21 MR. COX: Well, I understand that the Act is likely
22 to be up for consideration next year. What conclusions
23 members of Congress and others in the administration draw
24 from our action today is up to them. I hope they will think
25 it's as constructive and as important a step as we do.

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1 QUESTION: Following up on that, could you be a
2 little specific about this. By relegating the role, who
3 are you -- time complaints --

4 (Partially inaudible due to not being at a micro-
5 phone.)

6 MR. COSTLE: I think in creating this Institute,
7 we were all recognizing that health effects research in this
8 area will go on for a number of years. We have not even begun
9 to exhaust the research needed to be done to improve our un-
10 derstanding of these kinds of phenomena.

11 And obviously, that research will have to proceed
12 at its own appropriate pace which may or may not be convenient
13 for the political calendar of Capitol Hill or the periodic
14 process of reauthorizing and amending legislation. I think
15 it will take some time for the Institute to begin to produce
16 discrete research results that will then have a bearing on
17 Congressional debate.

18 But I also don't expect Congressional debate on
19 the Clean Air Act to be accomplished in one month, perhaps
20 even six months this time around. But I think one thing
21 Congress clearly will be looking at, and ought to be looking
22 at, are the kinds of institutional arrangements that we have
23 created in this country.

24 They are designed to get us better research results.
25 To get us a better scientific data base upon which to base our

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1 laws and regulations.

2 So I think that there's no coincidence to the timing
3 of this Institute with the fact that the Clear Air Act is
4 coming up for renewal this next year. But I think down the
5 road, in a very few years there will be a very happy coinci-
6 dence of the fact that we have an independent research insti-
7 tute adequately financed doing research work of high quality
8 and scientific integrity and to whom the Congress as well
9 can turn.

10 They've been, in many respects, the most obvious
11 victims of the adversarial research process in that they
12 get presented with conflicting data where common methodologies
13 have not been used to generate that data and are oftne caught
14 directly inthe cross fire.

15 And I think that this Institute is very much in-
16 tended to try to clarify that debate, again I will use my
17 favorite expression that Hank Schacht came up with two and
18 a half years ago, to generate a friendly set of facts. We
19 may argue about the facts but at least we will argue about
20 the same facts.

21 MR. COX: Yes?

22 QUESTION: (Inaudible due to not speaking into
23 the microphone.)

24 MR. COSTLE: The answer as to why it came first
25 to the auto industry was that an early conversation that

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1 Mr. Schacht and I had and we were also mindful, right at that
2 point in time, that a number of the companies were having to
3 begin under the Clean Air Act to do health effects research.

4 And there was an opportunity, it was a starting point
5 under the terms of the 1977 amendment, to really try to create
6 a new institutional arrangement that would be more efficient
7 and would also have public credibility. And so we just happened
8 to begin at that point.

9 There was nothing more magic about it than that.
10 But --

11 QUESTION: (Inaudible due to not being at the micro-
12 phone.)

13 MR. COSTLE: Well, let me finish.

14 It was also clear, as we began talking about it,
15 that if we could successfully create an institution like
16 this that it might, indeed, have applicability in other areas.
17 I think that there is a tremendous need to find new institu-
18 tional means by which industry and government can work together
19 on things.

20 And while still respecting the legislative responsi-
21 bilities the government is given and the responsibilities of
22 corporations in our economic system, I think we need new
23 institutions to begin to take as much out of the adversarial
24 context as we can.

25 And certainly, an absolutely first priority place

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1 to begin is the debate over scientific evidence and the gen-
2 eration of that data.

3 Clearly, I've been very mindful of the economic
4 conditions that apply particularly to the auto industry right
5 now and have, really, over the last two or three years. So I
6 know that they're not anxious to waste any resources in dupli-
7 cative work.

End Tape 1A

8 So I think that this, in some small way over time,
9 will help in that respect.

Begin Tape 1B

10 MR. MURPHY: Could I just add, Doug, that this idea
11 was put forward by Henry three years ago. At that time, the
12 economic situation as far as the industry was concerned was
13 not the way it is today. And so if you're talking about that,
14 I think that clearly was not the major consideration.

15 Now, obviously, all of us are desirous of being as
16 efficient as possible. In the final analysis, any money saved
17 here is going to benefit the consumer. And I think we ought
18 to recognize that. The individual companies would have to do
19 a certain amount of research and development of data on their
20 own in order to meet the requirements of the Clean Air Act.

21 And by doing it on some sort of a consolidated
22 basis so that -- particularly where it's done independently
23 so that the credibility is clearly established, and to use
24 the term that Doug used, the friendly set of facts developed
25 that everyone could agree on then you can have your

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1 disagreements about interpretation, and that sort of thing.

2 And I think it is in the interest, in the final
3 analysis, of the public at large; not any individual company,
4 not the industry. And I think the concept certainly does
5 lend itself to moving forward in having a better understanding
6 of all of our problems whether it affects the automobile
7 industry or the chemical industry or any other industry be-
8 cause in the final analysis it affects the air that we breathe
9 and then it affects every one of us in this country.

10 QUESTION: Doug, do you believe that this Institute
11 today would serve as a prototype for similar arrangements
12 with the Chemical Industry or, admittedly, the government, --
13 more greater than --

14 (Portions of the question are inaudible due to
15 the person not speaking into the microphone.)

16 MR. COSTLE: It just remains to be seen. We will
17 just have to -- I must say I think that we've got something
18 very special here. And I think that if it does -- if it
19 turns out that that's an accurate assessment, then time will
20 tell.

21 And I think that it, indeed, may find utility in
22 other areas. But I think you have to put one foot in front
23 of the other and one step at a time. And I want to see
24 this launched. But clearly, and I mean it quite sincerely,
25 we do need a concerted search in this country for

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1 institutional arrangements that will allow us to cooperate
2 more on things as between industry and government.

3 QUESTION: Would that be -- your successor?

4 MR. COSTLE: Indeed, it would.

5 MR. COX: I can't resist saying just a word to
6 underscore my conviction that the interest -- that's the real
7 reason for my interest in this undertaking. What we need
8 is more and more do-it-yourself undertakings that involve
9 parts of the private sector as well as parts of the government
10 section to get together.

11 The proper format for dealing with different prob-
12 lems may be different. And the representation from the
13 private sector, in one way or another, should involve all the
14 elements, not just parts of it. But my interest came about
15 in large part because of my involvement in labor-management
16 relations and sometimes government labor-management relations.

17 And I've seen, over too long a time to state the
18 number of years, the tremendous number of constructive things
19 that can be done through what I call quasi-public, quasi-
20 private do-it-yourself undertakings.

21 So I think that while there are no guarantees imbued
22 in a broad sense, much of the interest in this undertaking
23 is its broader possibilities in quite different areas where
24 the exact structure might not be duplicated but the same
25 type of thing could be done.

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1 QUESTION: How much money will the industry put in
2 initially?

3 MR. COX: Well, the Institute's plan look for us
4 spending in the first year on the order of \$3 and a half
5 million, almost surely no more. Ultimately, the Institute
6 estimates that its budget will be in the neighborhood of
7 \$12 to \$15 million, if all goes well.

8 The first year, EPA will put in a million. The
9 industry will put in the rest with the possibility of ob-
10 taining some money from foundations. As to the future years,
11 the exact division between EPA and the industry has not yet
12 been worked out.

13 The EPA has said it expects to continue significant
14 contributions. You can figure that a million is roughly
15 30 percent of the first year's budget. Or you can figure that
16 a million is a million and ignore the percentage.

17 (Laughter)

18 Or you can come up with something inbetween. We
19 have enough faith in the commitment of everybody so that
20 we're already going to put in on the basis of that somewhat
21 vague distribution.

22 QUESTION: Can you explain what effect this is
23 going to have on EPA's R&D programs? Are there any changes?
24 And, perhaps, some ideas or maybe suggestions on what the
25 first studies are the Institute is going to be undertaking?

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1 MR. COSTLE: I am not prepared today to respond to
2 the second part of your question in terms of specific studies.
3 I think that initially is something that the Institute people
4 are already working on. And we will work with them very
5 closely.

6 The EPA contribution this year will come from a
7 variety of EPA programs and will not come out of a specific
8 pot. And I have -- we have already solicited from the
9 Institute a grant application. And that is now being processed.
10 And I would hope to make that million dollars available within
11 the next two or three or four weeks, at most.

12 The money is there. I am prepared to commit it.
13 And I have enough confidence -- I share Professor Cox's confi-
14 dence in this in the sense that I think that the future funding
15 will take care of itself to the extent the Institute really
16 works.

17 And I think there will be -- that this will appeal
18 to the Congress as a very worthwhile way to do business in
19 this country.

20 QUESTION: How is this going to change EPA's --

21 MR. COSTLE: I don't believe that it will change.
22 It will clearly begin to make a difference in terms of our
23 future research priorities. But anything that is now cur-
24 rently underway we will have to obviously conclude. As you
25 know, a good part of that budget is already extramural or

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1 is contractor grant research.

2 MR. COX: Yes?

3 QUESTION: Are there any short-term objectives for
4 the Institute to review current data to see if the present
5 automotive emission standards that are established in the
6 current Act might be changed either maybe even more stringent
7 or even maybe more leniently?

8 MR. COX: The Institute will not be reviewing the
9 standards that have been set down by EPA. The Institute, nor
10 would I think, would go about determining what research to
11 do by saying what is the scientific base of a particular
12 regulation.

13 The approach of the Health Research Committee, I
14 feel quite sure, would be an attempt to determine on the basis
15 of their own expertise plus recommendations received from
16 EPA and from the industry and from other groups interested
17 in the environment -- we haven't mentioned them -- but their
18 recommendations and comments will be received by the Institute
19 and valued by it.

20 And on that basis, in terms of what appears to be
21 the most promising line in scientific research in terms of
22 likely importance and somewhat in terms of whether there's
23 an existing methodology available, the Committee will then
24 make its decision.

25 Bill, would you want to elaborate a little on that?

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1 MR. BAKER: What you're saying is right, Archie.
2 We will be trying to understand what the science and tech-
3 nology is to provide information on how to make decisions.
4 We will not be making rules and we have no basis for short-
5 range concentration but, rather, to understand what the total
6 correlation can be between health effects and auto emissions.

7 QUESTION: Mr. Costle, this Institute is being
8 set up on the basis of your --

9 (Inaudible portions of the question due to not
10 speaking into the microphone.)

11 MR. COSTLE: Obviously, I can't speak for my suc-
12 cessor. I don't know who that will be. But I think that
13 there is a bi-partisan concern in the area of environmental
14 protection and in an interest in quality, credible,
15 independently-conducted research.

16 So I would anticipate that there would be no prob-
17 lem in conception with respect to the Institute. I think that
18 really, we have tried very very hard over the last three years
19 to keep this thing out of politics. And I think we've suc-
20 ceeded in doing that.

21 And I think it important that it will have all that
22 much more value for our having done that.

23 QUESTION: Can you provide a bit of a time table
24 here? When is the health decision board going to actually
25 be functioning or when are they going to present a contract

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1 with respect to the ERA --

2 MR. COX: One reason Mr. Kennedy isn't here -- and
3 I'm going to answer your question in a moment. But one
4 reason Mr. Kennedy isn't here is that he's currently thinking
5 about the selection of an executive director. And he does
6 have a statement that I meant to read and carelessly failed
7 to read which is very important.

8 And it indicates his commitment to this undertaking.
9 He says that he will make it the primary commitment in addi-
10 tion to his duties as President of Stanford, the primary
11 activity that he engages in.

12 Now, to come back to your question. The staffing,
13 the selection of the members of the Health Research Committee,
14 we will reach back to go forward just as fast as we can push
15 it in the next few months. And sometime in the spring I
16 would hope that we would have the members of that committee.

17 Although it's perhaps not too optimistic to think
18 that the various grants or contracts would be made sometime
19 during the summer.

20 QUESTION: Where will the Institute be headquartered?

21 MR. COX: That has not yet been determined. It
22 seems likely that the headquarters will be near one of the
23 centers of the kinds of research capability that we're
24 interested in. Some of those are in the Cambridge area.
25 Some of those are in the Palo Alto area.

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1 You might note that I'm in the Cambridge area.
2 Don Kennedy is in the Palo Alto area. But beyond noting
3 those facts and beyond emphasizing the importance of locating
4 the Institute near the places where the kinds of research
5 can be done, we haven't chosen a site.

6 Thank you all very much for coming.

7 (Whereupon, the press conference was concluded
8 at 11:05 a.m.)

End Tape 1B

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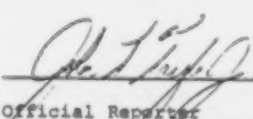
CASE TITLE: Press Conference: Health Effects Institute

HEARING DATE: December 12, 1980

LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence herein are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before United States Environmental Protection Agency and that this is a true and correct transcript of the same.

Date: December 15, 1980


Official Reporter
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Mr. SCHEUER. It's 1 o'clock and we've overstayed our time in this room.

I can't thank you enough and I can't express officially my admiration for the tremendously—well, it's really almost a revolutionary advance in problem solving. I wish that when I was a student at Swarthmore College and I was in a seminar on the problems of Government administration, we had had your institution as a case study. I mean, it is absolutely made to order for the political science student at the university postgraduate level. It is so creative and so innovative and so almost breathtakingly constructive that I am green with envy at not having been a participant from the beginning.

I deeply thank you all, and I hope we'll be in touch. We're going to try to reestablish some contact and some communication the next time you all come to Washington. I deeply regret that we don't have a couple more hours to chat with you, but the exigencies of congressional scheduling dictate otherwise.

So with repeated thanks, this hearing is adjourned.

[Whereupon, at 1:02 p.m. the hearing was adjourned.]

[Additional material submitted for the record follows:]

APPENDIX

STATEMENT OF
THE AMERICAN GAS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE RESEARCH,
AND ENVIRONMENT
COMMITTEE ON SCIENCE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES
ON THE JOINT U.S./CANADA REPORT ON ACID RAIN
March 13, 1986

The American Gas Association (A.G.A.) is a national trade association composed of nearly 300 natural gas distribution and transmission companies serving more than 166 million consumers in all 50 states. Together, these companies account for nearly 85 percent of the nation's total annual gas utility sales.

INTRODUCTION

On January 8, 1986, U.S. Presidential Envoy Drew Lewis and his Canadian counterpart, The Honorable William Davis, presented a joint report on "acid rain" to their governments. Their report recommended, in part, that the United States create a \$5 billion technology demonstration program to reduce acid rain in North America. Like so many acid rain proposals, the American portion of the report focused solely on installing technology to clean-up coal -- without mentioning the much less expensive option of using natural gas with coal. In contrast, the Canadian portion of the Joint Report of the Special Envoys on Acid Rain (Joint

Report) specifically noted the benefits of using natural gas with coal.

Natural gas has been -- and will continue to be -- the cleanest burning fossil fuel. It emits almost no sulfur oxides or particulate matter, and fewer nitrogen oxides than any other fossil fuel. Thus, burning some natural gas with coal can reduce air pollutants just as effectively as flue gas desulfurization or scrubbers, for a fraction of the cost. Although acid rain and environmental protection are now major public policy goals, the costs of environmental compliance continue to escalate. In this era of federal budgetary restraints, we must develop cheaper alternatives than a new and expensive technology demonstration program. One such alternative is to use natural gas for one of its best and most valued purposes -- environmental compliance.

Of course, there are many ways to reduce sulfur oxide (SOx) and nitrogen oxide (NOx) emissions from coal, oil, wood chips or wastes. Plant operators will not prefer to use natural gas to offset pollutants in all cases, but owners and operators must be free to choose the most cost-effective control option for their plants. Thus, acid rain proposals that focus on specific coal cleaning technologies, (such as recommendation A of the Joint Report) or statutes that prohibit or dissuade users from using certain fuels (such as the Fuel Use Act, the incremental pricing provisions of the Natural Gas Policy Act (NGPA) and certain Department of Defense (DOD) appropriations bills), merely

raise the cost of environmental compliance. As we have said time after time, one of the first steps that Congress can take to reduce sulfur oxide emissions is to repeal the uneconomic prohibitions on natural gas use in the Fuel Use Act (FUA) and in DOD appropriations bills. Congress must also repeal the incremental pricing provisions of the NGPA, that raise the price of natural gas to industrial boiler owners.

In contrast to many acid rain proposals, such repeal would not cost American taxpayers a penny. Indeed, repeal would save tax dollars. A recent National Defense Council Foundation Report, entitled Congressionally Mandated Energy Waste at the Department of Defense (February 24, 1986), found that three special interest pieces of legislation force the Department of Defense to use coal or oil in many facilities.* Over time, these restrictions will cost the American people from \$2.1 billion to as much as \$5 billion. The Report (attached) states that:

"Taken together, these actions actually require the wasteful expenditure of billions of dollars over the next few years These congressional actions are clear examples of unwarranted misuse of taxpayer funds, obstruction of free competition in the energy industry and government over-regulation. In the absence of any meaningful national security justification, there is absolutely no reason for the Congress to dictate which fuels DOD should use."

*Specifically, these actions are:

- 1 The 1982 Military Construction Codification Act prohibits the DOD from using natural gas in new, large heating

Clearly, Congress must take immediate steps to stop this gross waste of tax dollars and to permit DOD to use natural gas, or other economical and environmentally benign fuels.

The Fuel Use Act is another wasteful and environmentally unsound statute. A.G.A.'s analysis, Projected Economic and Environmental Impacts of Retaining the Fuel Use Act Through the year 2000 (1984-12) shows that "failure to repeal FUA will decrease domestic GNP while increasing unemployment and the trade deficit." The cost of generating electricity with new coal units (equipped with scrubbers to control sulfur oxides) is much higher than the cost of generating electricity with natural gas-fired combined cycle and cogeneration systems (which inherently emit little or no SOx). Thus, FUA could cost future

systems on military installations within the Continental United States, regardless of the cost advantages or environmental benefits of using natural gas.

- 2 The Defense Appropriations Subcommittee Report for the FY 1986 Defense Appropriations bill placed a freeze on all oil-to-gas conversions at DOD facilities. This freeze will block all conversions until a comprehensive report is submitted to the Defense Appropriations Subcommittee -- possibility several years from now. (Although the mandate appears only in the subcommittee report, and is not law, it effectively operates as law since DOD officials are extremely reluctant to act contrary to the wishes of their appropriations subcommittee.)
- 3 The FY 1986 Defense Appropriation (as contained in the FY 1986 Continuing Resolution) requires an increase of 1.6 million tons per year in DOD coal usage at bases in the U.S. by 1994 -- more than doubling DOD's coal use in the United States. Moreover, in order to protect the anthracite coal industry from free competition, DOD is ordered to buy 302,000 tons of anthracite coal per year whether it can use the coal or not.

electric ratepayers up to \$1.6 billion/year more than they would have paid if their utility had the option of generating electricity with natural gas. Furthermore, even with control technology, increasing coal use would cause substantial additional pollution: 8.9 million tons of SOx between 1984 and 2000, plus 4.8 million tons of particulates, 5.8 million tons of NOx, .5 million tons of water pollution, and 383 million tons of solid wastes, over the same period (see Appendix 1, attached). Thus, the first Congressional step toward reducing sulfur oxide air pollution should be to repeal restraints on natural gas use.

CLEAN COAL TECHNOLOGIES

There are many different clean coal technologies. Some of them use mechanical systems to remove SO₂, while others use clean burning natural gas to offset SO₂ emissions. Operators should be free to choose the least expensive of these technologies based on circumstances at a particular plant. The following examples of gas-coal technologies were taken from A.G.A.'s statements before four different Congressional Committees supporting the creation of a \$400 million Clean Coal Technology Fund for research projects.*

* See, Statements of May 29, 1985 before the Subcommittee on Energy Development and Applications of the House Science and Technology Committee; before the Subcommittee on the Interior of the House Committee on Appropriations; before the Subcommittee on the Interior of the Senate Appropriations Committee; and before the Subcommittee on Energy Research and Development of the Senate Energy and Natural Resources Committee.

(1) Select Gas use

Select gas use (select use) refers to a relatively new concept in fuel combustion: the burning of natural gas with less environmentally attractive fuels in the same or separate combustion units for environmental control purposes. As one option, select use may involve the combustion of gas and another fuel (most often coal) in the same combustion unit as a fuel mixture. A more common approach, which is less difficult from an engineering perspective, involves the concurrent combustion of gas and some other fuel in separate combustion units, then averaging the emissions from the two separate sources. This latter approach (termed a bubble), when approved by the Environmental Protection Agency (EPA), may be used to meet the air quality guidelines of a State Implementation Plan (SIP). A third approach (not currently sanctioned by the EPA) entails the seasonal substitution of gas for other fuels. Coal or high-sulfur oil could be burned for a portion of the year and natural gas could be burned for the remaining portion of the year to offset the coal- or oil-derived emissions.

Some of these concepts have advanced from the theoretical stage to the implementation stage. More than two dozen select use applications have been implemented, including four cases of concurrent combustion in a single unit. Furthermore, at least four major institutions are conducting additional research into the simultaneous

combustion of gas and other fuels in a single unit. The research relating to gas and coal combustion is focused in three areas: (a) reburn technology to reduce NO_x and SO_x emissions; (b) gas use to assist the burning of coal-water mixtures; and (c) gas use to assist oil-to-coal conversions.

(2) Reburn Technology

Reburn is a post-combustion pollution control method that can be used to reduce NO_x levels found in the combustion products of coal-fired electric utility or industrial boilers. Natural gas (or another fuel) is injected into the exhaust from a coal-fired boiler, creating a fuel-rich zone in which the NO_x reacts and produces free nitrogen; air is then added to complete the combustion process. Preliminary testing indicates that the reburn process using gas could easily reduce NO_2 emissions by 50 percent. The Gas Research Institute and the Energy and Environmental Research Corporation are currently conducting research on the reburn process to determine: (a) how close the reburning fuel should be relative to the combustion zone; and (b) how much time should be allowed for reburning before air is injected into the process.

(3) Assisting Coal-Water Mixtures

Coal-water mixtures were originally proposed as a way to displace foreign oil with domestic coal. More recently, however, it has become evident that coal-water mixtures may

appeal to those who use coal but want to avoid the adverse environmental effects from direct combustion of dry coal.

Unfortunately, the use of coal-water mixtures may lead to substantial deratings, slagging, fouling, flame instability and other problems. However, recent gas industry sponsored research indicates that cofiring coal-water mixtures with natural gas offers an economic and environmentally attractive solution to these problems. We cite as examples three recent papers:

- (1) J. Dooher, T. Kanabrocki, and D. Wright, Co-firing of Coal Water Slurries with Natural Gas, Adelphi Center for Energy Studies, Adelphi University, Garden City, New York.
- (2) Robert H. Essenhigh, E.G. Bailey, Kyu-il Han, and Zongwen Li, Performance Characteristics of a Hot-Wall Furnace Fired With Coal Water Slurry (CWS) Using Gas/Air Atomization, The Ohio State University, Columbus, Ohio.
- (3) Alex E.S. Green, Coal-Water Mixtures - A Market Opportunity for Natural Gas, University of Florida, Gainesville, Florida.

(4) Oil-to-Coal Conversions

In addition, natural gas can make it economically and environmentally advantageous to convert oil-fired boilers to coal. A research team at the University of Florida is already using natural gas to assist a full scale oil-to-coal conversion. We cite for example:

- (1) A.E.S. Green, An Alternative to Oil: Burning Coal with Gas (Gainesville, FL, University Presses of Florida, 1981).

THE JOINT REPORT OF THE SPECIAL ENVOYS
ON ACID RAIN

The Joint Report of the Special Envoys on Acid Rain was presented to President Reagan, and to Canadian Prime Minister Brian Mulroney, on January 8, 1986. The Joint Report recommends, in part, the creation of a \$5 billion technology demonstration program to clean-up coal. We disagree with that recommendation because it ignores the less expensive gas-coal options, such as select use, that were discussed infra. However, the Joint Report also recommends that existing regulations and laws be amended to give industry more flexibility to meet environmental goals. We agree with this recommendation. Rather than focusing on a new and expensive government program, we believe that policymakers should turn their attention to revising statutes and regulations already in effect, so that industry can choose the least expensive compliance options. We are convinced that gas-coal technologies, and conversions from residual oil to gas, can cut sulfur oxide pollution substantially, and at much lower costs than retrofitting coal units with scrubbers.

The authors of the Joint Report believe that an acid rain program that makes high sulfur coal economically unattractive may have adverse socio-economic effects on high sulfur coal mining regions. For this reason, the Joint Report recommends a \$5 billion program to make this coal marketable. This is unnecessary. Although operators who

use one of the gas-coal technologies that we described earlier, or some other innovative strategy, will displace some high sulfur coal with natural gas, the gas-coal option is so much cheaper than straight coal (plus mechanical cleaning technology) that operators may actually install more high sulfur coal boilers, and increase coal use in the aggregate. By presuming that any acid rain program must preserve 100% of even potential coal markets, the Joint Report forces the nation to adopt the most expensive environmental control techniques. Yet there are many socio-economic benefits from increased natural gas usage that are not even considered in the Joint Report. They are:

- Lower Costs. Using natural gas to offset SO_x emissions from coal units tends to have low capital requirements. In many cases, this strategy has the lowest total costs of any control option. The costs of SO_2 reductions by using natural gas with coal have been calculated to vary from a very low \$50/ton of SO_2 reduced to over \$1000/ton, with many applications in the \$200-\$400/ton range. By comparison ICF, Inc., an independent consultant, estimates a range of costs, from \$250 to \$2000/ton of SO_2 removed, for seven straight coal alternatives. Thus, natural gas/coal strategies are at the low end of the cost curve.
- Lowers Many Pollutants Simultaneously. Natural gas use simultaneously reduces many pollutants (e.g., sulfur oxides, nitrogen oxides, reactive hydrocarbons, particulates, carbon monoxide, carbon dioxide). It produces virtually no SO_2 or particulate matter, about one-third as much NO_x as coal, and one-half as much NO_x as high sulfur residual oil. In addition, gas combustion produces no sludge or ash, in sharp contrast to the scrubbers and precipitators that are used to control emissions from coal.
- Uses More High Sulfur Coal. The Joint Report says that, because coal washing removes less than half

the sulfur in high sulfur coals, "its usefulness as an acid rain control technique is very limited." However, by using both washed coal and some natural gas (30:70 gas:coal ratio) SO₂ emissions would be reduced by approximately two-thirds, while local coal would continue to provide 70 percent of the plants' energy input.

- Supply Security. Natural gas can displace foreign oil. For example, switching twelve New England powerplants from oil to either natural gas or a gas/coal mix could reduce the region's use of imported oil by 15 percent, while improving the U.S. balance of payments by \$1 billion per year.
- Technical Reasons. Natural gas ameliorates operating problems caused by other control measures. For example, switching to low sulfur coal may cause substantial unit derating, while also increasing particulate emissions and solid waste disposal problems. Scrubbers -- the control technique favored in the Joint Report -- also cause efficiency losses.
- Availability of Natural Gas. Shortly after the NGPA was enacted, a natural gas deliverability surplus, or "bubble," developed in the United States. To the great surprise of many, this "bubble" grew rapidly and has persisted. Lower natural gas demand, coupled with supply stability, has led to 2.5 trillion cubic feet (Tcf) of shut-in U.S. gas. Furthermore, U.S. buyers have contracted for 1 Tcf of Canadian gas which they cannot take. This domestic and Canadian surplus has led to hardship among gas producers and to higher consumer prices because of take-or-pay prepayments for shut-in gas. The principal solution to both the take-or-pay problem and the decline in producer exploration is to sell more gas. More gas demand will alleviate take-or-pay for gas buyers and cause a "demand pull" for gas sellers that will put them back in the business of drilling for new supplies.
- Quick Sulfur Oxide Reductions. Most large oil burning units already have gas burning capability. Thus, substituting natural gas for high sulfur residual oil can reduce acid rain immediately, whereas other technologies require many years for equipment design, testing, and installation. For example, the state of Wisconsin recently enacted acid rain legislation which focuses on the 43 largest emitters of SO₂ in the state. Of these sites, at least 16 are already hooked up to gas and

could use gas to immediately reduce SO₂ emissions by 70%.

CONCLUSION

The U.S. really shares two problems with Canada. While acid rain is a problem on both sides of the border, so is an over-supply of natural gas. Surely our Canadian neighbors would eagerly accept a sulfur oxide reduction program that also absorbs excess natural gas supplies. Using more natural gas is not only good environmental and energy policy, but good international policy as well.

For the nation to realize the benefits of competitive energy prices for both gas and electricity, an improving balance of payments, and a healthy natural gas production, sales, and transportation industry, we need to make natural gas readily available as an energy option to industry and electric power generators. As we have said many times before, this means repealing the Fuel Use Act, incremental pricing under the Natural Gas Policy Act, and restrictions on natural gas use in Department of Defense appropriations bills.

There is a real link here between good energy policy and good environmental policy. Increasing natural gas usage can help solve two problems at once.

APPENDIX 1

Summary Table I

PROJECTED IMPACTS OF RETAINING THE FUEL USE ACT, 1985-2000
-- COAL CONVERSION SCENARIO¹

<u>Gas Use Restricted</u> <u>(TBtu)²</u>	<u>Peak</u> <u>Year</u> <u>Impacts</u>	<u>Cumulative</u> <u>Impacts</u> <u>1985-2000</u>
Electric Powerplant	1,121	7,976
Large Industrial	1,903	18,183
Total	3,024	26,159
 <u>Incremental Capital Investment</u> <u>(\$1984 Millions)</u>		
Electric Powerplant	\$1,480	\$26,280
Large Industrial	3,260	17,420
Total	\$4,740	\$43,700
 <u>Incremental Cost of Electricity</u> <u>(\$1984 Millions)</u>		
Total	\$1,553	\$11,500
 <u>Incremental Pollution</u> <u>(Thousands of Tons)</u>		
Sulfur Dioxide	1,068	8,940
Particulates	547	4,850
Nitrogen Oxides	670	5,790
Water Pollution	54	470
Solid Wastes	44,163	382,930

1. Assumes gas use restricted by the Fuel Use Act is replaced by increased coal consumption.

2. Trillion Btu; 1000 TBtu = 1 Quadrillion Btu (Quad).

Sources: See Appendices I-III.

Summary Table II

PROJECTED IMPACTS OF RETAINING THE FUEL USE ACT, 1985-2000
-- IMPORT SCENARIO¹

<u>Gas Use Restricted</u> <u>(Tbtu)²</u>	<u>Peak</u> <u>Year</u> <u>Impacts</u>	<u>Cumulative</u> <u>Impacts</u> <u>1984-2000</u>
Large Industrial	1,903	18,183
Electric Powerplant	1,121	7,976
Total	<u>3,024</u>	<u>26,159</u>
 <u>Decline in GNP</u> <u>(\$1984 Millions)</u>		
Large Industrial	\$114,560	\$1,068,180
Electric Powerplant	12,869	91,565
Total	<u>\$127,429</u>	<u>\$1,159,745</u>
 <u>Decline in Domestic Employment</u> <u>(Thousands of Workers)</u>		
Large Industrial	273	1,369
Electric Powerplant	7	108
Total	<u>280</u>	<u>1,477</u>
 <u>Increase in Trade Deficit</u> <u>(\$1984 Millions)</u>		
Large Industrial	\$114,560	\$1,068,180
Electric Powerplant	12,869	91,565
Total	<u>\$127,429</u>	<u>\$1,159,745</u>

Note: Projected declines in GNP and employment due to retaining FUA account for 2.3 percent of total projected GNP in 2000, and 1.1 percent of total employment. See Appendices IV and V.

1. Assumes decline in domestic production of electricity and industrial products due to restricted gas consumption is entirely offset by importing foreign goods and electricity.
2. Trillion Btu; 1000 Tbtu = 1 Quadrillion Btu (Quad).

Source: See Appendices IV and V.



NATIONAL DEFENSE COUNCIL FOUNDATION

"In Defense of Free Enterprise, Country and Constitution"

L'Enfant Plaza Box 23397
Washington, D.C. 20026

Administrative offices at:
Barrister Square
106 S. Columbus Street
Alexandria, VA 22314
(703) 836-3443

February 24, 1986

*** ISSUE ALERT ***

CONGRESSIONALLY MANDATED ENERGY WASTE AT THE DEPARTMENT OF DEFENSE

A Billion Dollar Boondoggle

As pressure to trim the deficit increases, the prospect of Draconian budget cuts looms large on the horizon. Given this fact, it is astounding that the Congress continues to impose prohibitions and requirements on the Department of Defense (DOD) which could cause it to waste billions of dollars on its energy purchases. The Federal Government is already the largest single user of energy within the U.S. economy, and the lion's share of that use supports DOD defense requirements. Therefore, any action which affects defense energy outlays is bound to have a significant impact on both overall federal spending and the economy as a whole.

The problems arise from politically motivated Congressional actions which effectively prohibit DOD from making cost-saving energy choices. Taken together, they actually require the wasteful expenditure of billions of dollars over the next few years.

These Congressional actions are clear examples of unwarranted misuse of taxpayer funds, obstruction of free competition in the energy industry and government over-regulation. In the absence of any meaningful national security justification, there is absolutely no reason for the Congress to dictate which fuels DOD should use.

The first of these actions prohibited the use of natural gas in new, large heating systems on military installations within the Continental United States (CONUS), regardless of the cost advantages or environmental benefits of using gas. The second has placed a freeze on all oil-to-gas conversions at DOD facilities. This freeze will block all conversions until a comprehensive report is submitted to the Defense Appropriations Subcommittee -- possibly several years from now. The third action, a part of the FY 1986 Defense Appropriation requires an increase of 1.6 million tons per year in DOD coal usage at CONUS bases by 1994 -- more than doubling DOD's burning of coal in the United States. Moreover, in order to protect the anthracite coal industry from free competition, DOD is ordered to maintain anthracite purchases at 302,000 tons per year whether it can use the coal or not.

All of these requirements prevent the military from taking advantage of exceptionally low natural gas prices which are currently available in many regions of the country. Worse, 35 out of 37 bases already targeted by DOD for increased coal use would achieve the increase by conversion from some other fuel which is already in place. In other words, the mandated increase in coal usage contained in the 1986 law will require the conversion (premature retirement) of some existing, inexpensive gas-fired facilities to capital-intensive coal-fired facilities merely to meet the target consumption figures. Together these restrictions mean that under almost no circumstances would gas-fired systems be installed, no matter how economically beneficial such a move would be.

To give some perspective to the scope of the problem, in most instances, a gas-fired boiler can be installed for approximately twenty to thirty percent the cost of an equivalent coal-fired unit. If underground steam lines are included (which is often the case), the cost of the coal installation would be dramatically higher. DOD has estimated the cost of conversion to coal to average \$37 million per affected installation. Thus, the 1.6 million ton per year bituminous/anthracite coal conversion program alone will conservatively cost at least \$1.4 billion (DOD estimate) for new facilities -- possibly much more -- while resulting in increased non-fuel operating and maintenance costs. Assuming that coal use will produce a 50¢/MMBtu operating and maintenance (O&M) cost savings (including fuel costs) -- an extremely generous assumption given the higher operating costs for coal and the recent declines in gas prices -- the total annual cost savings from the \$1.4 billion coal conversion program would be \$17-\$22 million. This means it would take from 64 to 82 years to pay back the taxpayer's \$1.4 billion investment. This reality was clearly recognized in DOD's August 30, 1985 report to Congress on the coal conversion program, in which DOD stated:

"Many of the proposed conversions are not cost-effective under current and projected fuels prices."

When all three restrictions are considered, the net cost to the nation could easily be several billion dollars.

Besides costs there are also a variety of tactical and strategic considerations which make natural gas a preferable alternative for use at military installations. Compared to other energy forms, it is relatively invulnerable to interdiction by small scale military attacks, it is found in large quantities domestically, and is not characterized by central storage or processing facilities which would create highly visible targets of opportunity. In addition, its relative fungibility vis-a-vis oil products helps it add an element of flexibility to military capability which is lacking in coal-fired facilities.

In short, natural gas provides an ideal energy option for military planners, should be given the fullest possible

consideration in strategic thinking, and should be an option available to base commanders. Congressional prohibitions on its use, or mandates which curtail the prospect of its use, make neither economic nor strategic sense, and should be eliminated.

BACKGROUND

The enactment of mandatory limits on federal spending under the Gramm/Rudman/Hollings law represents a culmination of the growing consensus that greater fiscal responsibility must be achieved. Perhaps the most telling evidence of this consensus is the fact that fully half of any mandated deficit reductions must come from military outlays -- an area previously considered immune from the Administration's budget-cutting orientation. Although some of the support for curtailing military spending in the new budget-cutting targets was generated by reports of \$500 hammers, and \$6000 toilet seats, there are far more significant areas in which real savings can be realized that warrant serious attention. Among the most promising is the area of energy.

The importance of defense-related energy outlays in the overall federal budget is underscored by the fact that DOD uses almost five times as much energy as all other agencies combined, and that the overall percentage of domestic energy use accounted for by the Federal Government has been steadily growing. In spite of conservation measures, DOD's energy use has grown by 10 percent over the last five years. Given the size and continued growth of federal energy consumption, it is clear that great care should be given to assuring that economic, and not political factors, drive federal energy decisions. This fact makes all the more curious three Congressional actions which not only limit the flexibility of defense planners to take advantage of changing market conditions, but which virtually mandate needlessly large outlays for energy and energy facilities at bases within the Continental United States (CONUS).

In the 1982 Military Construction Codification Act, Congress enacted a prohibition on the use of natural gas in new, large heating applications at CONUS bases. Then, in Report Language to the 1986 Defense Appropriations bill Congress placed a freeze on all oil-to-gas conversions at DOD facilities. Finally, in the 1986 Defense Appropriation (as contained in the FY 1986 Continuing Appropriations Resolution) Congress mandated that coal use be increased 1.6 million tons per year at CONUS bases by 1994. By enacting these restrictions, the legislators ensured that monies spent for heating systems, hot water, and a variety of other purposes be greater than is necessary.

THE POLITICS OF DOD ENERGY REQUIREMENTS AND RESTRICTIONS

It has become painfully evident that these legislated restrictions on DOD use of natural gas are in large part politically motivated, i.e., stimulated by constituent pressure to restrict free market competition. Despite the fact that natural

gas prices have been steadily declining and despite the fact that the nation currently faces a significant oversupply of the fuel, Congress has taken action to effectively curtail the ability of military base commanders to take advantage of these favorable market conditions.

Consider, for example, the previously noted FY 1986 Defense Appropriations bill and its requirement that DOD increase its use of domestic coal by some 1.6 million tons annually. The legislation specifically includes an initial \$25 million "to implement immediately... to rehabilitate and convert" steam plants for coal use. In other words, DOD was told to move quickly, and it was anticipated that conversions of existing facilities would be required. The coal conversion program is among the clearest recent examples of politically driven energy decisions causing an enormous waste of precious defense dollars, since such an increase effectively requires that some existing oil and gas-fired boilers be replaced, at great cost, with ones capable of burning coal. The appropriation even goes so far as to specify that DOD must purchase at least 302,000 tons per year of anthracite coal -- a difficult-to-use coal mined almost solely in Pennsylvania. Only 2100 miners, 1.1% of the nation's total, are employed in anthracite production.

It is clear from the legislative history that the DOD faces pressure to increase coal use in CONUS quickly as part of a deal with coal state legislators to remove current legislative requirements to use U.S. coal at our military bases in Europe. Indeed, DOD appears to have "proposed" the swap in a report to Congress dated August 30, 1985. It's not difficult to see why DOD would be taking whatever steps it could to rid itself of the highly onerous and damaging requirements for use of U.S. coal at our European bases.

Congress not only prohibits U.S. bases in Europe from switching from coal to other energy sources but requires that the European bases use U.S. coal shipped in U.S. flag vessels. Further, Congress is now actually requiring DOD to build a one-year coal stockpile in Europe at a cost of \$62,566,800. The cost of transport alone is \$17,500,000. To quote the DOD report, "This total cost does not include local handling costs and maintenance costs such as sealing of the bituminous stock to prevent deterioration." In other words, what coal is not damaged or stolen in shipment is being paved over when it arrives in Europe.

In summarizing the economic impact of these requirements the 1985 DOD Energy Management Plan states:

"The cost of coal use is increased by two factors. First, U.S. forces in Europe would probably turn to other, cheaper energy sources in the absence of Congressional direction otherwise. Second, breakage during transport reduces the usefulness of the coal purchased in the United States and consumed overseas."

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Poor economics are not the only concern. Our coal use poses serious diplomatic problems due to growing environmental concern in Germany, and is frequently in violation of German law. To again quote the DOD report:

"German officials at all levels are unalterably opposed to the use of coal (any kind, from any country) where connection to a local district heating system is an available alternative... The Department of Defense is becoming increasingly unable to comply with Congressional direction on U.S. coal use in Europe and German law."

In view of these serious economic and diplomatic problems DOD has consistently requested relief from legislatively mandated coal use in Europe. In frustration, they seem to be offering dramatically increased coal use in CONUS as an alternative. As serious as the European problem is, mandated coal use makes no sense for domestic bases either.

First, coal-fired boilers cost from four to five times as much as ones burning natural gas due in large part to the need to equip them with complex pollution abatement equipment. Second, on balance, because coal is a difficult fuel to work with, the reliability of coal-fired units is lower than that of comparable units burning natural gas. In addition, they require far more maintenance, and produce a large residue of ash and other by-products which must be disposed of. Therefore, the notion of retrofitting existing heating systems on CONUS installations to use coal is virtually a mandate for waste and inefficiency. As in Germany, it will collide with environmental regulations in the U.S. Since no economic justification can be found for such a policy, it must be concluded that its roots lie in a different arena: politics and particularly the politics of legislators with coal mining constituencies; i.e., protectionism and a "made in Washington," "sole source" mentality at a time when DOD should be free to look for the most efficient and economical energy sources.

Much the same appears to be the case with the Report Language to the Defense Appropriations bill of 1986. This is the language that requires extensive reporting requirements by DOD to the House of Representatives Defense Appropriations Subcommittee before military bases can convert existing CONUS facilities from oil to natural gas. As is the case with the mandated increase in coal use, the limitation on natural gas use makes no economic sense. Currently, there are a number of military installations in the U.S. which are located in areas where a surplus of natural gas exists, and where prices are extremely low. As a consequence, military bases in these areas could realize large savings by converting their primary heating of buildings and water to natural gas. However, local commanders are prohibited from making such a move by the new 1986 restriction -- until a comprehensive DOD study is completed and submitted to Congress.

Members of Congress are requiring these detailed cost benefit analyses to justify a base commander's requests to switch to gas, even though it is apparent that conducting such studies could take years, and that more than ample empirical evidence already exists to justify the switch. In short, the call for new studies and Congressional review constitutes nothing more than an attempt to impose paralysis through analysis on the efforts of local commanders to improve their energy efficiency.

Finally, the 1982 Military Construction Codification Act prohibits the use of natural gas in new heating installations. This prohibition complements the 1986 CONUS coal conversion requirement and the 1986 Report Language imposing extensive reporting requirements for existing facilities. These three Congressional actions handcuff cost-effective DOD decisions for both existing and new military bases (see Table 1). A point that must be emphasized about the restrictions imposed on natural gas use, is that they reduce the options available to local commanders as they try to make informed decisions. While there may be specific instances in which coal, oil, or even electricity enjoy a cost advantage over natural gas, the key is to allow all options to be considered, and then have decisions made on the basis of the best possible economic thinking. Allowing politics to take precedence over common sense and empirical evidence certainly is not the best way to achieve this goal.

COST TO THE NATION

The cost to the nation of the three legislative domestic DOD fuel choice restrictions is significant. According to studies performed for the U.S. Environmental Protection Agency (EPA), the cost of a typically-sized (100 MMBtu per hour input) new coal-fired boiler with scrubber is roughly \$14 million, as compared to \$2.5 million for a comparable gas boiler. The coal conversion program will require installation of the equivalent of 60-75 boilers of this size, at a 1985 dollar cost probably approaching \$1 billion. (In fact, it will likely be necessary to add the equivalent of 18-22 additional boilers to compensate for the lower efficiency of coal heating -- 45% versus 65% for natural gas.)

When we include the cost of steam lines and other facilities which coal use may require, however, the cost will be much greater. For example, the conversion of Fairchild Air Force Base in Spokane, Washington is reported to have cost \$18.5 million, while the conversion of Malmstrom Air Force Base in Montana has cost \$31 million. Both bases have experienced operational difficulties in the conversion to coal. The coal conversion program will require the equivalent of 140-175 installations the size of the Malmstrom conversion, plus units to compensate for efficiency loss. On that basis the cost of the conversion program could realistically exceed \$5 billion over the next eight years. By comparison the official DOD conversion cost estimate for the program is \$1.4 billion.

Even accepting DOD's \$1.4 billion cost estimate, the likely economic payback at today's energy prices is absurd.

- (1) It is well recognized that operating and maintenance costs for gas fired facilities are typically 50¢ - \$100/MMBtu lower than for comparable coal-fired facilities. For example, a report prepared for the U.S. Corps of Engineers in 1984 regarding U.S. facilities in Europe used a range of 62¢-96¢ for the difference. (Special Report to Congress of the United States On The Feasibility of Replacing the Necessary Equipment at USAREUR to Establish Coal as the Major Energy Source with Alternative Fuel Analysis, Philadelphia, PA, Kling Lindquist, Inc., for the U.S. Corps of Engineers, May 1, 1984, Table 4-3.)
- (2) Based upon current contract prices being paid by DOD for bituminous coal shipped to Europe and reducing those prices \$8/ton to allow for lower prices reportedly paid by DOD for U.S. delivery (Ibid., p.3-2), DOD appears to be paying roughly \$1.90/MMBtu for bituminous coal delivered in CONUS. With delivered spot and incentive rate gas prices of \$3.00-\$3.50 widely available to large users today, a fuel price differential between gas and coal of \$1.10 - \$1.60/MMBtu is likely.
- (3) On this basis a total operating and maintenance cost differential between gas and coal of 10¢ - \$1.10 MMBtu results. Taking a 50¢/MMBtu difference as realistic, the payback period on a \$1.4 billion "investment" would be 64-82 years. (The range takes into account variations in coal quality.)
- (4) Even assuming far less favorable gas prices the payback period would be unacceptably long by any standard. For instance, in 1984, before natural gas spot prices began their significant decline, the Federal government paid, on average, \$2.00/MMBtu more for natural gas than for coal. On that basis the payback period would be 22-32 years.

These figures are for the conversion program only. They ignore the larger total maintenance and operating costs and lesser reliability of facilities fueled by alternatives to natural gas. They also ignore the unnecessarily high cost of meeting, without natural gas, new energy requirements at the 800 CONUS military facilities. When all of these are considered, the cost to the nation could easily be billions if not tens of billions of dollars.

STRATEGIC IMPLICATIONS

In addition to its general advantage in terms of economics, natural gas also enjoys a number of characteristics which make it preferable from a strategic standpoint.

In reviewing the military use of various energy alternatives from a strategic standpoint, a number of facts become readily evident. First, it is preferable to rely on secure domestically based energy sources than it is to rely on ones which must be imported from abroad, and which are therefore vulnerable to interruption in time of national emergency or conflict. Second, given the current concern over the danger of terrorist attacks, energy sources which have greater resistance to such assaults are to be preferred over ones more vulnerable to interdiction. Finally, energy options which provide a maximum of flexibility are preferable to those with limited applications. In all of these areas, natural gas wins high marks.

Natural gas is characterized by a high degree of what economists call "fungibility" with oil. What this means is that gas can be readily substituted for oil in most applications. This is obvious in the case of use as a boiler fuel, but it also can be readily substituted for oil in other applications, including transportation. In fact, the use of either dual-fuel capable vehicles, which could burn either conventional motor fuels or natural gas, or even of vehicles exclusively designed to use natural gas, is an option the military has continued to study, and which is gaining increased support.

A second, and perhaps most important point, is that, compared to other energy forms, the natural gas system is less visible and less vulnerable to interdiction by terrorists. Gas is stored in the ground, and therefore does not require highly vulnerable storage terminals, or loading facilities either on site, or near the point of use. In addition, it is transported by a network of pipelines which comprise in excess of one million miles, and which largely is buried underground. Moreover, local gas utilities must routinely deal with small scale leaks, or damage to these lines, and as a consequence, there is already in place a national infrastructure to quickly, and efficiently deal with any temporary break. Further, the size and complexity of the system is such that even should a pipeline break occur, routing gas supplies around it is a relatively simple task. A final point, is that natural gas is produced from literally hundreds of thousands of individual wells, dispersed throughout the nation, and again, this makes it less likely for any single group of terrorists, or even for several groups to be able to interdict the gas delivery system for any significant amount of time.

In addition to the relative security advantages inherent in the production and delivery system for natural gas, it also enjoys the advantage of requiring no further processing from its natural state before it can be used in most cases. Therefore, there are no refineries which offer targets of opportunity to terrorists, and no danger of losing access to a fuel because it cannot be converted into a useful form.

When considering the advantages of natural gas from a strategic point of view, it is also important to consider the

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effect its use has on other alternatives, and on other aspects of the economy which would become important during time of conflict. For example, the availability of natural gas as an alternative, both to heat bases, and provide power, as well as an alternative motor fuel reduces the likelihood that the Strategic Petroleum Reserve, which is intended for civilian use, would have to be commandeered for use by the military. Also, the widespread use of gas at domestic defense installations minimizes the likelihood that increased levels of military activity would be hampered by the need to move increased amounts of coal by rail, thereby reducing the availability of rail transport for other military purposes.

It follows then, that not only from an economic perspective, but from a strategic perspective as well, allowing the military to make the fullest possible use of natural gas as both a boiler fuel, and, potentially, as an alternative motor fuel in non-combat vehicles makes good sense. Restrictions on such use run contrary to both sound economic thinking and sound strategic policy.

CONCLUSION

In the final analysis, it is clear that political considerations are creating significant barriers to the wider defense applications of natural gas, and that these barriers are contrary to the national interest. Restrictions on the use of natural gas on military bases should be removed, and in fact, the wider use of gas should be encouraged. Similarly, the use of ploys such as unneeded studies (while they would eventually confirm existing data which indicate that natural gas is an economically preferable alternative for heating and other boiler applications on military installations) merely serve to delay the ability of the Department of Defense to act on this information, and should be discouraged. Finally, Congress should recognize that in these times of growing austerity, natural gas provides one means of reducing defense outlays while simultaneously enhancing national security. As such, it is an option which cannot be ignored, must not be discouraged, and ought to be promoted.

- Milton R. Copulos

TABLE 1

LEGISLATIVE ACTION	TYPE OF FACILITY	IMPACT
1982 Military Construction Codification Act	New Heating Installations	Prohibits Gas Use
1986 Defense Appropriation Report Language	Existing Facilities	Stops Conversions From Oil to Gas
1986 Defense Appropriation	Existing Facilities	Requires Conversions to Coal



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 2 1986

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

Honorable James H. Scheuer
Chairman, Subcommittee on Natural
Resources, Agriculture Research
and Environment
Committee on Science and Technology
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of April 14, 1986, requesting additional information on the Environmental Protection Agency's (EPA) FY 1987 research budget request. I am pleased to forward EPA's responses to your follow-up questions on Don Ehreth's March 13, 1986, testimony before your Subcommittee.

If you have questions on the material we are providing, please feel free to call Mark Hague on 382-4213.

Sincerely,

A handwritten signature in cursive script, appearing to read "Howard M. Messner".

Howard M. Messner
Assistant Administrator
for Administration and
Resources Management

Enclosure

USER FEES

Question: The FY 87 budget request indicates that EPA will begin a "pilot program" to charge user fees under the pesticides, toxics, and water quality programs. Describe the proposal and explain the rationale behind the user fees.

Answer: The President's Budget for FY 1987 describes EPA's plan to collect fees in four areas, which will properly shift the burden of paying for Federal services to the recipients of those services, such as private business concerns. These fees include:

- ° Pesticides registration and reregistration
- ° Toxic Substances Premanufacture Notification
- ° Ocean Disposal user fees
- ° Quality Assurance (QA) costs in the research programs for Water Quality and Drinking Water, as a pilot effort to externalize quality assurance costs.

The Agency believes that substantial revenues could be obtained and that the proposals are consistent with OMB Circular A-25 and with the Independent Offices Appropriation Act (31 U.S.C. §9701), which states that the sense of the Congress is that each service provided by an Agency should be self-sustaining to the extent possible.

The Administrator has convened a Task Force to examine the issue Agency-wide and has brought the matter before a State/EPA committee to obtain State input to make the fees as effective as possible.

Question: Who will pay the user fees?

Answer: The recipients of EPA's services will pay the fees. In most cases, these are private sector users, such as the chemical manufacturing industry. Public entities (municipalities for Ocean Disposal, State laboratories for research QA fees) may also be charged.

Specific fee payers will be described in regulations that will be issued to establish the fees.

Question: How much revenue does EPA expect to generate from this "pilot program"?

Answer: Estimates in the Appendix to the President's Budget for FY 1987 total \$21 million.

- ° Pesticides\$15 million
- ° Toxics.....\$2 million
- ° Ocean Dumping\$4 million

The Office of Research and Development estimates that its QA fee would bring in \$1 million during FY 1987.

Question: Will these revenues be returned to the EPA research program, or will they go to the Treasury? If the former, how are the revenues reflected in the FY 1987 budget request?

Answer: Research program. For 1987, EPA hopes to have the Appropriations bill modified to allow research collections to be credited to EPA's principal appropriation accounts.

In anticipation of that legislation, the budget requests for Quality Assurance functions in Water Quality and Drinking Water were reduced by \$1 million.

All programs. The Administration also hopes to submit authorizing legislation to create a Special Fund to receive receipts from Agency fee collections. The legislation would include such programs as Pesticides, Toxic Substances and Ocean Dumping. Our request for Budget Authority for these three programs would not change for FY 1987 whether legislation were enacted or not.

Question: What criteria will EPA use to determine whether the "pilot program" is a success or failure?

Answer: Included among these criteria are Agency and public comments on the proposed regulations that will establish the fees.

When the Agency evaluates the program after it has operated for a period of time, we will review it in five areas: environmental impact, financial contribution, effect on States, administrative burden, and economic impact on the user community.

MAXIMUM CONTAMINANT LEVEL (MCL)

Question: The EPA has recently raised the maximum contaminant level (MCL) in drinking water for fluoride, which has been linked to bone disease at high levels. Did the EPA conduct any new research on the health effects of high levels of fluoride before determining to raise the MCL for fluoride?

Answer: EPA conducted a research project to determine the effects of various levels of naturally occurring fluoride on dental mottling in children ages 7-12 years and 14-18 years. The results indicate that there is a direct and nearly proportional relationship between fluoride levels in drinking water and average fluoride intake. Mottling of the dental enamel was strongly associated with increases in water fluoride levels and the dental caries rate varied inversely with fluoride levels in drinking water. Since dental mottling is not considered a health effect, we believe EPA is justified in raising the fluoride levels.

Question: Does the EPA have any plans to conduct any such health effects research in the future?

Answer: No, EPA is not planning to conduct any additional health effects research on fluoride.

INDOOR AIR

Question: What are EPA's present plans regarding a national indoor air field survey? What pollutants will be monitored?

Answer: Plans for the indoor air field survey are currently undergoing technical review by member agencies of the Committee on Indoor Air Quality (CIAQ). The present plan focuses on a national probability survey for Volatile Organic Compounds (VOCs). This plan is intended to define on a nationwide scale the magnitude of the indoor problem for selected pollutants. In addition to VOCs, pollutants of interest include respirable and inhalable particles (PM_{2.5} and PM₁₀), formaldehyde (HCHO), nitrogen dioxide (NO₂), and to some extent heavy metals and semi-volatile organic compounds. In order to qualify the pollutant measurements, the air exchange rate in each residence will be measured while the residents maintain diaries of their activities. This information will be supplemented by a resident questionnaire of indoor sources and combined to produce the information needed to determine statistically the levels of exposure of the population indoors in U.S. residences. Currently, sufficient data do not exist to permit accurate assessment of the problem on a nationwide basis.

Question: How much will the survey cost?

Answer: The current plan projects a study of 1500 residences nationwide selected at random from 50 geographical subregions. The sampling would require seven days in each residence, with the total effort extending over 24 calendar months. The total extramural cost of the field survey is estimated at up to \$4 million.

Question: How will the survey results be used to determine the health effects of exposure to indoor contaminants?

Answer: We will compare the measured concentrations to literature values for which health effects have been published. Specifically, we will use the published unit cancer risks to estimate cancer rates for the population (70 years of exposure to 1 mg/m³). Also, the measured concentrations of VOC's will be used to establish mixture concentrations for use in clinical chamber studies. We will not collect health effects data directly from residents of the monitored homes.

Question: What will the survey show beyond what EPA has already learned in the Total Exposure Assessment Monitoring Program?

Answer: The survey is designed to determine the mean indoor concentration in the nation of VOCs and selected other pollutants. The TEAM study measured personal exposures (some of which

were all indoors) in depth in several cities. These cities were not chosen at random but were purposefully selected to be "close to industry" and "far from industry". We will measure in random locations at random times so that our data base will present a national picture. The field study questionnaire will have more depth than the TEAM study which should enable us to identify homes with new or uncontrolled sources. TEAM uncovered the problem. The National Survey will tell us whether it is local or national, and if so, what its magnitude is.

INDOOR AIR

Question: In addition to the indoor air field survey, what research will be conducted to assess the health effects of indoor air pollution?

Answer: EPA's Office of Health Research (OHR) will continue to conduct several ongoing epidemiological investigations that were begun in FY 1985. The objectives of these studies, which have been jointly funded through the Congressional add-ons and EPA's base program, include:

1. Assessment of the accuracy and reliability of biologic markers, direct monitoring and questionnaire data as measures of exposure to indoor air pollutants; and
2. Assessment of acute respiratory symptoms and pulmonary function effects of indoor air pollutants in children and other sensitive populations.

The indoor air health research program also includes a continuing effort to develop capabilities to conduct clinical studies using chamber facilities. These studies are designed to ascertain the health effects of controlled exposures to indoor air pollutants. They have been funded primarily from EPA's base program with some augmentation from the Congressional add-ons. Studies planned for FY 1986 include assessments of the acute inhalation toxicologic and neurotoxic effects of volatile organic compounds (VOCs). Chamber studies are also planned for methodological research to quantify the relationship between exposure and dose for VOCs and other pollutants. These studies are conducted in support of EPA's National Indoor Air Field Study.

Small laboratory chamber studies are being used to develop various test methods needed to assess health effects of indoor pollutants. In FY 1985, for example, extraction and sampling methodology studies were begun in order to develop a standard protocol for measuring mutagenic activity of indoor air particles. Studies to assess the activity of kerosene heater emissions and side stream cigarette smoke were also begun.

Finally, personnel from the indoor air health program will be involved in planning for the National Health and Nutrition Examination Survey (NHANES III) for the National Center for Health Statistics so that national survey information may be obtained on indoor air pollution.

DIFFERENCES BETWEEN EPA AND DOE RADON PROGRAMS

Question: What are the differences between the EPA radon program and the DOE radon program?

Answer: The radon research programs of EPA and DOE differ in two main respects. First, they are different because of the missions of the two agencies. DOE's radon research results from the concern for energy conservation, primarily the possible adverse human health effects of weatherization of structures and its long-term concern about the health effects of human exposure to radiation. EPA's radon research arises specifically from the need to assist states in identifying and reducing the risks to human health from naturally occurring radon.

Second, the two agencies' research programs differ in that DOE generally performs basic research on the potential health-related effects of energy sources. EPA, in contrast, concentrates its efforts on applied research on techniques and methods that will have practical applications in reducing those health effects.

COORDINATION OF RADON RESEARCH

Question: How do EPA and DOE coordinate their radon programs?

Answer: Because DOE has had a long-standing radon program, EPA coordinates its research with DOE in many ways. One formal avenue of coordination is the Interagency Committee on Indoor Air Quality (CIAQ), which includes a radon workgroup co-chaired by DOE and EPA. This workgroup includes other interested Federal agencies such as the Tennessee Valley Authority, Bonneville Power Administration, and the Centers for Disease Control. Another formal avenue of coordination is the Committee for Interagency Radiation Research and Policy Coordination (CIRRPC) established by the Office of Science and Technology Policy (OSTP). EPA and DOE serve on both the Science Panel and the Radon Subpanel of CIRRPC; this representation has reinforced the coordination developed within the CIAQ radon workgroup.

DOE and EPA also communicate informally through the close lines of communication that have developed among staff at DOE's Office of Conservation and Renewable Energy, EPA's Office of Radiation Programs, DOE's Office of Energy Research, and EPA's Office of Research and Development. Frequent communication among the staff in these offices has enhanced the coordination of research, public information, and applied research programs. DOE and EPA senior management also discuss Federal agency activities through the CIAQ and on an informal basis.

In many of the DOE/EPA staff interactions and the interagency meetings, EPA has made it a point to describe its planned and current research and has received comments and suggestions from DOE and other agencies. This communication helps to ensure that the Federal projects are complementary and not duplicative. In general, DOE efforts on radon are characterized by basic research whereas EPA's radon action program focuses on applied research and on the transfer of research information to both operational programs and activities, and to State and local government and the private sector.

Specific examples of DOE/EPA coordination include: DOE's participation in a two-day EPA workshop on objectives for a national radon assessment; DOE's involvement during the development of EPA's strategies for radon activities on both a national level and also specifically in the Reading Prong; joint funding of work at Lawrence Berkeley Laboratory on important features of soil as a source of radon; DOE's assistance in the development and review of measurement protocols for indoor radon; and DOE's participation in the planning and implementation of a quality assurance program for indoor radon measurements.

COORDINATION OF RADON RESEARCH (CONTINUED)

In addition, staff on EPA projects to demonstrate low-cost mitigation techniques for radon are exchanging work plans and site visits with DOE staff on similar projects, especially those at the Bonneville Power Administration. This exchange of information and experience increases the number of geographical areas from which data on house types and mitigation effectiveness are available. A joint project on diagnostic mitigation studies at EPA project sites is also being planned.

EXPLORATORY RESEARCH GRANTS PROGRAM

Question: How many new grants were awarded under EPA's Exploratory Research Program in FY 85? In FY 86?

Answer: EPA's Exploratory Research Program awarded approximately 55 new grants in FY 1985. Approximately 55 new grants were awarded in FY 1986.

Question: How many new grants could be awarded under the proposed FY 87 budget?

Answer: In FY 1987, the emphasis of the Exploratory Research grants program will be on ongoing research rather than new efforts. The grants program will not award any new grants in response to a general solicitation, although EPA may consider awarding new grants on a limited, case-by-case basis. Funds will be used instead to extend previously awarded grants, because the Agency believes that this is the most effective use of resources. The FY 1987 President's Budget reflects the Agency's overall priorities.

JOURNAL ARTICLES

Question: How many peer-reviewed journal articles are published each year by EPA-funded research?

Answer: The research program has published an average of 435 peer-reviewed journal articles each year. This represents about one-third of the products of EPA's research program. In addition to journal articles, the research program produces over 900 research reports, assessment reports, proceedings, internal reports and unpublished papers each year.

Question: How many of them come from EPA's Exploratory Research Program?

Answer: The Exploratory Research Program has produced an average of 180 published journal articles each year.

EXPLORATORY RESEARCH GRANTS PROGRAM

Question: What percentage of applications are being awarded grants under the Exploratory Research Program?

Answer: Fourteen percent of applications that are submitted to the Exploratory Research Program are awarded grants.

Question: How does that percentage compare to the percentage of applicants receiving awards under the NIH peer-reviewed grant program?

Answer: The percentage of applicants receiving awards under the NIH peer-reviewed grant program is 11% higher than EPA.

Question: How many of the applications not funded in FY 85 and FY 86 were found to have scientific merit and relevance to the EPA mission?

Answer: In FY 1985, sixty-five applications found to have scientific merit and relevance were not awarded. In FY 1986, sixty-one were not awarded which were found to have scientific merit.

CONTROL TECHNOLOGIES FOR SO_x AND NO_x

Question: What research is EPA presently conducting on technologies to control sulfur dioxides and nitrogen oxides, other than the limestone injection multistage burner?

Answer: During FY 1986 EPA is planning to continue development of control technologies which will reduce emission of sulfur oxides (SO_x) and nitrogen oxides (NO_x). This effort will include a study to determine the effectiveness of humidified duct injection of highly activated sorbents to remove SO_x and an assessment of improved spray drying equipment to increase SO_x removal efficiencies at reduced costs. In the NO_x area, we are planning to determine the effectiveness of various combustion modification techniques to reduce emissions. These include the use of low NO_x burners in industrial boilers, evaluation of reburning techniques for various combustion processes and a fundamental combustion research (FCR) program to develop an understanding of the combustion process as it relates to NO_x formation. The FCR program will also determine the effectiveness of various control technologies in removing NO_x from the combustion of highly nitrated hazardous waste.

Question: What would happen to the funding for such technologies in the FY 87 budget?

Answer: Due to the Agency's shift in priorities from criteria to non-criteria pollutants, some of the control technology work for criteria pollutants is being phased out, and therefore the 1987 program on NO_x and SO_x control technologies is being reduced by \$853,000 to \$2.3 million. However, we will continue to support the development of New Source Performance Standards and will continue the FCR program, primarily in-house. As noted above, SO_x removal techniques will be evaluated, and work will continue on the evaluation of reburning techniques for NO_x control. In addition to EPA-supported research in these areas, some SO_x and NO_x control technology issues are also being addressed as part of the Department of Energy's Clean Coal technology demonstration.

LIMB DEVELOPMENT

Question: Is the requested FY 87 funding sufficient to ensure the completion of a full-scale demonstration of a tangentially-fired LIMB?

Answer: At the present time, it is not possible to determine the adequacy of the FY 1987 funding to ensure completion of a demonstration of LIMB in a tangentially-fired boiler. We are estimating that the total cost of the project will be approximately \$20 million. In the past, we have been able to get our industrial partners to contribute about 50% of the project cost. Additionally, the Environmental Protection Agency (EPA) and the Department of Energy (DOE) are currently discussing the possibility of jointly cooperating on the funding of a tangentially-fired demonstration by combining resources within EPA's LIMB program with resources within DOE's Clean Coal Technology (CCT) program.

Question: If not, is there any evidence that development on a tangentially-fired LIMB will be continued by the private sector?

Answer: We do not know whether the private sector would continue the development of a tangentially-fired demonstration without additional funding from the public sector. Currently, both the EPA LIMB and the DOE CCT programs have solicitations which could result in a demonstration of the LIMB technology on a tangentially-fired boiler. However, until the proposals are received and evaluated, we cannot determine how much the private sector will be willing to contribute for a co-funded demonstration of LIMB on a tangentially-fired boiler.

ACID RAIN--ANALYSIS OF EXISTING STATUTES

Question: On January 8, 1986, Presidential Envoy Drew Lewis and his Canadian counterpart, the Honorable William Davis, presented the Joint Report of the Special Envoys on Acid Rain to their respective governments. The Report recommends, on page 45, that:

"[b]oth the United States and Canada should review their existing air pollution programs and legislation to identify opportunities, consistent with existing law, for addressing environmental concerns related to transboundary air pollution."

Has EPA made an analysis of which statutes and regulations could be used to address transboundary air pollution? If so, please list these statutes and regulations, and describe prospective changes.

Answer: In December 1984, the EPA completed a preliminary analysis of existing Clean Air Act (CAA) authorities and actions which affect sulfur emissions (see attached report, An Integrated Sulfur Strategy Study, Concept Paper). This was done to better understand the interrelationship which exists between these actions and their potential for achieving additional reductions.

Question: If EPA has not done such an analysis, does the Agency intend to undertake an analysis of statutes and regulations as a result of the Report? If not, why not?

Answer: We believe the Integrated Sulfur Strategy Study can be expanded upon to respond to the Special Envoys' recommendation.

INTEGRATED SULFUR STRATEGY STUDY

CONCEPT PAPER

Office of Air Quality Planning and Standards

December 20, 1984

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Executive Summary

This paper reports on a four month conceptual study of the possibility of an integrated sulfur oxides management strategy. The study examined the multiple environmental problems associated with sulfur oxides (SO_x). For the purposes of this study the effects of SO_x were divided into two geographic scales: 1) "local," i.e., vicinity of a major point source or a single urban area, and 2) "regional," i.e., multi-county to multi-state regions. The review indicated that any strategy which focused on only one scale could ameliorate effects on that scale while doing little (or even aggravating) for effects on the other scale.

The study identified some 16 pending regulatory and policy decisions as having the potential for affecting SO_2 emissions. Of these, seven now appear to be major in terms of their effect on emissions. The current regulatory program was found to not have the potential to produce emission reductions of the same order of magnitude as those contemplated in many potential regional scale programs (i.e. several million tons per year). However, some of the pending major regulatory decisions do have such a potential. Although most recent thinking on these decisions has tended to emphasize regulatory stability, the Stack Heights regulation is an important exception. This regulation, when implemented, could represent a major departure from the status quo.

This study also briefly reviewed current analyses of sulfur oxides. The on-going analyses have contributed significantly to our understanding of SO_x effects and alternative strategies. However, there are still some gaps and deficiencies. The most significant of these is that most analyses

have examined only one scale of effects or one strategy. This conceptual study proposed an analytic framework for comparing strategies on both scales. The framework proposed involved a simple matrix displaying the way in which individual sources are affected by different strategies. Such a matrix would facilitate co-ordination of existing strategies and ease the development of new integrated strategies.

The conclusions drawn from the work to date can be summarized as follows:

- The potential for confronting utilities with "moving targets" is high. Although recent Agency decisions have emphasized regulatory stability, the Stack Heights regulations is an important exception.
- Local scale programs as now conceived do not meet many possible regional objectives,
- The effects of regional scale programs on local scale goals/constraints are not well understood, and
- Integrated strategies to meet multiple objectives on both geographic scales appear possible

Recommendations for further work are presented. These include the development of the matrix discussed above. Work on this has already been initiated. Analyses to better determine the impact of a key pending regulatory decision (SIP Emission Limit Averaging) are also being evaluated.

Integrated Sulfur Strategy Study
Concept Paper

I. Introduction

This paper reports on the initial results of a four month conceptual study assessing the possibility of an integrated sulfur oxides management strategy. In the context of this study an integrated strategy is one which is explicitly designed to meet multiple environmental objectives. This study was largely conceptual and did not involve any new, quantitative analyses.

It is generally accepted that the emission of sulfur oxides (SO_x) to the atmosphere can produce a variety of health and welfare effects both in the immediate vicinity of the emission source and at considerable distances (500 km). The local scale health and welfare effects are comparatively well understood and quantitative objectives [i.e. National Ambient Air Quality Standards (NAAQS)] have been set. Over the past decade and a half EPA together with State and local agencies has successfully implemented a variety of control programs to reduce the local scale effects of sulfur oxides. As a result, national sulfur oxide emissions have declined by some 17% since 1975. Regional scale effects, on the other hand, are not as well understood and represent a more recent concern. As yet no regional scale objectives have been agreed upon, and no regional control programs implemented. However, regional scale objectives are being considered and various pieces of legislation have been proposed to address perceived problems. If such objectives were agreed upon, an important consideration in designing a strategy to achieve them would be the integration of such a regional sulfur strategy with the already existing local scale sulfur strategies. This paper reports on considerations which would go into such an integrated sulfur strategy.

Sulfur oxide emissions result primarily from the combustion of sulfur bearing fuels and the processing of sulfur bearing ores. Sulfur oxides are generally emitted as sulfur dioxide (SO_2), but can be transformed in the atmosphere into sulfates (SO_4). Under current U.S. conditions some 85% of all SO_2 emissions come from just three major source categories: utility power plants, industrial boilers, and primary non-ferrous smelters. This concentration of emissions in such a limited number of source categories makes it all but certain that the same set of sources will be considered for control under both regional and local strategies. This could potentially lead to sources being subjected to a succession of emission limits. The potential for "moving targets" makes it all the more important that strategies be integrated.

As noted above EPA and state efforts at controlling SO_2 emissions to meet local scale goals have been successful. There are now only 63 counties which do not attain the SO_2 NAAQS. This success does not, however, mean that the local scale programs are now completely static. To the contrary, there are now pending within the Agency a wide variety of SO_2 policy and regulatory decisions. These decisions arise either from periodic reviews mandated by the Clean Air Act or from court decisions. In addition, there are several key decisions arising from state actions in the context of the State Implementation Plan (SIP) program. Given the potential for a regional scale program, there is often a tendency to evaluate decisions on local scale objectives with possible regional scale objectives in mind. In this regard there are two equally valid policy perspectives a decision-maker might take. The first perspective would hold that since a regional scale program may be in the offing, one should try to maintain the status

quo as much as possible so as not to confront sources with a series of "moving targets". The second perspective is that since a regional program may be in the offing, one should make decisions that result in incremental progress (in the form of emissions reduction) toward eventual regional goals. Recently, decision-makers have tended to adopt the first perspective, although this is not true in all cases. Clearly whichever policy perspective the decision maker adopts, it will be important to understand how local and potential regional scale programs might interact.

It should be emphasized that this study was designed to assess the possibility of designing an integrated sulfur strategy. In this context, an integrated strategy presupposes agreed upon regional and local scale goals. As noted above there are no agreed upon regional goals. Until agreement is reached on regional goals a single definitive integrated strategy is not possible. However, the concepts and analytic framework discussed below should provide valuable information to decision-makers considering possible regional goals.

This study was initiated with a brief examination of the multiple environmental effects associated with sulfur oxides (Section II below). The range of policy/regulatory decisions now pending was catalogued and analyzed (Section III). The various on-going studies of the sulfur oxides problem(s) were reviewed (Section IV). A simple analytic approach for comparing strategies on both scales was tested for a limited number of sources (Section V). Finally, based on this work it was possible to draw some preliminary conclusions and make recommendations for further work (Section VI).

II. Overview of Multiple Environmental Problems

A. Introduction

Central to the examination of the potential for developing integrated sulfur oxides strategies is the recognition of the variety of known and potential effects associated with SO_2 and its transformation products. The goal of any improved strategy should involve more efficient protection against the full range of effects. The purpose of this section is to provide 1) a brief cataloging of the major known and potential effects categories, 2) the geographical and temporal scales on which they occur, and 3) a set of mainly qualitative criteria by which alternative strategies might be judged in this conceptual phase as well as the assessment of the potential for more quantitative evaluations in the future.

In the context of control strategy development, it is convenient to discuss the effects of sulfur oxides and their transformation products on three geographical scales: 1) the vicinity (<20 km) of major point sources, 2) urban areas, involving multiple point and area sources, and 3) multi-county to multi-state regions. For this discussion the first two scales are grouped and termed "local" and the remaining is termed "regional."

Table II-1 presents a listing of the major effects categories associated with sulfur oxides emissions according to the scales as well as the principal form of sulfur oxide pollution associated with such effects, the temporal patterns of interest, any alternative goals put forward to minimize the effects, and an indication of the criteria by which programs to reduce such effects might be judged, given presently available assessment tools. As evidenced in the Table, the pollutant(s) of concern vary with the scale of interest. On a local scale, most of the effects are associated

TABLE 11-1. MULTIPLE ENVIRONMENTAL EFFECTS OF SULFUR OXIDES

Scale	Category	Effects Levels Pollutant	Time Period	Applicable/ Potential Goals	Alternative Criteria for Evaluation
Local (<20 km from major point sources, urban areas)	Health				
	Aggravation of bronchitis, other respiratory disease, premature mortality	≥ 0.19 ppm SO_2	24 hours	0.14 ppm 24-hour MAQS	Areas not attaining standard
	Chronic respiratory disease	≥ 0.07 ppm SO_2	annual	0.03 ppm annual MAQS	Areas not attaining standard
	Aggravation of asthma, asthma	≥ 0.5 ppm SO_2	5 to 60 minutes	0.25 to 0.75 ppm 1 hour, staff range	Percentage of sen- sitive population - exposures of concern
	Willow Foliar injury, yield reduction in vegetation	≥ 0.5 ppm SO_2	2 to 4 hours	0.5 ppm 3-hour MAQS	Areas not attaining standard, economic benefit estimates
	Yield reduction in trees	.02 to .05 ppm SO_2	multi-year	0.03 ppm annual MAQS	Areas not attaining standard
	Elimination of some lichens (local & regional)	0.005 to .02 ppm SO_2	multi-year	N.A.	Regional levels of SO_2
	Materials damage	Background to >0.3 ppm SO_2 prime sulfuric acid fallout	multi-year event	0.3 ppm annual MAQS N.A.	Areas not attaining standard, economic benefit estimates N.A.
	Acid Deposition Related Aquatic Systems—changes in water chemistry, loss of fish, other system changes, indirect health	>20 to 30 kg/ha as wet sulfate	multi-year, seasonal	10 to 20 kg/ha/yr as sulfate	Potential number of sensitive lakes affected
	Terrestrial Systems— crop damage forest damage	N.A. Unknown	seasonal multi-year	N.A.	Reduction in risk associated with current sources, economic benefit estimates
Regional (100 to >100 km, multiple sources)	materials damage	SO_2 , acid	multi-year	N.A.	population weighted visibility changes, economic benefit estimates
	Visibility Impairment (Regional Haze)	Fine particle sulfates ≥ 100 $\mu\text{g}/\text{m}^3$	daily to seasonal	8 to 25 $\mu\text{g}/\text{m}^3$ seasonal staff range	reduced mortality morbidity risk N.A.
	Health/PM Standard	Fine particle sulfates	daily to long term	proposed PM ₁₀ standards	
Climate		Fine particle sulfates	long-term	N.A.	

with direct effects of the principal sulfur oxide emitted, SO_2 . On a regional scale effects are also associated with SO_2 , but in large part involve atmospheric as well as ecosystem transformation products including sulfuric acid, other fine particulate sulfates, as well as acidic precipitation.

The most important control strategy implication to be drawn from this division of geographical scale and pollutants of concern is that any strategy that focuses on just one of the two scales could ameliorate effects of concern on that scale while doing little (or even aggravating) effects on the other scale. Thus, for example, tall stacks can be used to meet ground level SO_2 goals, but enhance long range dispersion and transformation of SO_2 on a regional scale; switching from coal to oil can reduce regional emissions but increase local sulfuric acid levels, and decreasing stack heights without changing emissions can decrease regional transport but aggravate local scale effects. The major effects categories associated with both local and regional scales of interest are briefly discussed in the following sections.

B. Local Scale Effects

As discussed in the SO_2 -PM criteria document and the SO_2 staff paper, the major local scale effects associated with SO_2 include, 1) health: a) effects on respiratory mechanics and symptoms, b) aggravation of existing respiratory and cardiovascular disease, c) effects on clearance and other host defense mechanisms, and d) increased mortality in sensitive groups and 2) welfare: a) damage to vegetation, including yield reductions, foliar injury, and changes in ecosystem species and diversity, and b) materials damage. Table II-1 indicates the concentrations and averaging times associated with these effects categories. The current ambient standards, established in 1971, represent goals that would eliminate or minimize these effects.

Measured by these standards, major progress has been made from 1970 to the present in reducing the local effects of SO_2 , with only 63 areas in non-attainment. At issue in the ongoing standard review process, however, is a set of recent studies indicating potential effects in exercising asthmatics and atopics near major point sources, even when the current standards are attained. Effects levels and staff range of interest are indicated in the Table. Analyses conducted to date suggest that implementation of the current standards provides substantial protection against those effects, with a maximum of 2 to 4% of asthmatics living in the vicinity of major point sources experiencing exposures of concern over the course of a year. Integrated strategies should be examined for the extent to which they maintain or improve upon or the protection against those peaks afforded by the current standards.

C. Regional Scale Effects

Table II-1 lists a variety of effects that are associated with regional sulfur oxides emissions. Unlike the local SO_2 case, for the most part no consensus environmental goals have been established for these effects and, in many cases, effects levels are undefined. In large measure, this is due to the large uncertainty associated with source-receptor relationships and in pollutant-effects associations. Given this situation, alternative strategy development may be based on efficiency of regional emissions reductions and evaluations can be focused on the extent to which strategies reduce indicator pollutant loadings in areas thought to be sensitive to the regional effects of concern. Because the geographical location of sensitive "receptors" and time scale of interest varies with the effects of concern, it is important to consider all of the effects, and not concentrate on a single set. Each of the major regional effects categories is briefly summarized below.

1. Acidic deposition - A variety of effects have been postulated as being associated with acidic deposition, but substantial scientific controversy surrounds most. The best information is related to effects on aquatic ecosystems, which are thought to be limited to sensitive lakes and streams that have little capacity for neutralizing incoming acids. "Sensitivity maps" and "resources at risk" criteria that have been developed to date indicate potentially sensitive systems in portions of the northeast U.S. and Canada, southern Appalachia, and portions of the upper midwest as well as some regions in the west that have historically low levels of acidic deposition. An improved national inventory is being developed for the 1985 assessment. Based on cross sectional comparisons, sulfate loadings "effects levels" and goals have been advanced, but are subject to scientific debate.

Effects on terrestrial systems are much less clear. At present no substantial effects on crops have been demonstrated with only one cultivar of soybeans showing yield reductions. It is hypothesized, however, that acid deposition may play some role in the apparent decline in some eastern forest tree species, but this is by no means demonstrated. If such a relationship were shown, the potential benefits of sulfur reduction could be substantial.

Effects of acid deposition on materials are plausible, but at present are more readily related to local and regional scale SO_2 concentrations. Quantitative assessments and improved inventory of resources at risk.

Post deposition health effects have been suggested as being derived from 1) leaching of toxic metals (notably lead) into drinking water and 2) buildup of mercury and other metals in edible fish. The extent of any such effects appears small and should occur in sensitive areas indicated by the severity of sensitive aquatic ecosystems.

2. Particulate Matter (PM) NAAQS - Regionally elevated sulfate levels derived from SO_2 emissions can contribute to violations of the 24-hour and annual NAAQS for particulate matter. A number of counties that may exceed the current and potential future PM NAAQS are located in midwestern and southeastern regions experiencing high sulfate loadings. The proposed revisions to the PM standard would tend to increase the relative importance of fine particulate sulfates in areas that exceed the standard. A reduction in regional sulfate levels, together with associated ammonium ions and bound water, would mean reduced expense of attaining and maintaining the PM NAAQS from local sources. Because some, not readily characterized, health risks from sulfates and other fine particles potentially exist at the moderate concentrations found in polluted eastern urban areas, reductions in sulfate levels over broad populated eastern regions would also reduce any such health risk. Attempts at quantifying this risk reduction have been made using cross-sectional macro-epidemiological studies of sulfate-mortality associations as a basis. Although controversial and highly uncertain, the results of such analysis to date suggest that the range of benefits from such risk reduction could be small to quite substantial.

3. Visibility - Effects of regional sulfur oxide emissions on visibility are related to their influence on fine particle air quality. The major transformation products that can affect visibility significantly are sulfuric acid and various ammonium sulfate aerosols. These form a large fraction of the fine particle loadings that dominate visibility impairment from man-made sources.

Usually, good visibility is valued most highly in natural settings such as parks and wilderness areas. Congress mandated visibility protection of 156 class I Federal Areas as a national goal in Section 169A of the

Clean Air Act. Most of these areas are in the west where the number and quality of scenic vistas make visibility a particularly important air quality related value. Of the 23 most heavily used national parks and monuments, however, 11 are in the east. Land managers in the Smokies, the Shenandoah and some other areas in the region of high sulfates have reported that episodic haze impairs visibility in these areas. Future actions designed to address the regional haze issues in these areas would most likely involve regional sulfur oxide emissions.

Studies of the value of visibility and perception in urban settings indicate that the public cares about visibility even in these settings and is willing to pay for maintaining or improving it. However, there are only three such studies and for a variety of reasons it is difficult to derive from them a precise estimate of the value the public would assign to visibility improvements. In the review of particulate matter criteria and standards, the EPA staff and Clean Air Scientific Advisory Committee (CASAC) recommended consideration of a fine particle secondary NAAQS to protect eastern visibility. The CASAC noted the strong linkages between control strategies for fine particles and strategies for acidic deposition. Recent analyses, based on regional modeling and willingness to pay studies have estimated that visibility benefits of sulfur oxides control strategy may be a substantial fraction of control costs.

III. Regulatory Review: A Catalogue of Decisions

A. Introduction

There are now pending or upcoming in the Agency a variety of policy and regulatory decisions relating to the control of SO₂ emissions. With only a few exceptions these decisions relate to local scale objectives. For the most part these decisions are being pursued independently, on different time schedules, and often with only a limited perception of how they may interact to affect the same sources. A key factor in determining the degree to which they interact is the amount of discretion the Agency possesses. In many of these decisions the Agency currently possesses considerable discretion both with respect to the stringency and the timing of the outcome; in others it has discretion on stringency only. This assessment catalogued and examined some 16 pending or upcoming regulatory decisions (see Table III.1). Each of the decisions is discussed in some detail in Appendix A. Readers wishing a discussion of the key issues and timing involved in an individual decision are referred to the Appendix. The discussion which follows here addresses some of the general observations which can be made about all the decisions and then concentrates on the seven more major decisions.

B. Sixteen Decisions: General Observations

A first observation is that the bulk of the decisions arise from the SIP program and the New Source Performance Standards (NSPS) program. At the outset, it is important to note that the decisions listed under "SIP Policy Actions" are national policy decisions in the SIP program and do not include the many individual SIP revisions that are in process. Individual SIP revisions are submitted by states to EPA and may affect individual sources or classes of sources within that state. Each SIP revision taken in isolation, generally, does not have much impact on total U.S. emissions

of SO_2 . However, collectively these actions are important and can significantly affect total emissions. In the majority of cases, states are revising emission limits upward to allow the use of higher sulfur fuels. In many of these cases, however, the revised limit merely reflects what is already occurring in actual practice. In such cases there may be a "paper" increase in emissions but no actual increase. In 1982, for example, SIP revisions showed a "paper" increase of 475,000 TPY but the actual increase was estimated at only 14,000 TPY. Although local factors are extremely important in motivating SIP revisions, national SIP policy changes do produce SIP revisions as well. The focus here is on national policy decisions.

A second general point is that a number of the decisions relate in various ways to the problem of variability in sulfur emissions (e.g. items 6, 9, 13, and 14 in Table III.1). For combustion sources the variability in SO_x emissions is the result of the variability of coal sulfur contents. In its SIP related aspects the Agency has delayed a national decision on variability so that it could be considered at the same time as decisions on the ambient standard and possible regional strategies. Although sources and state agencies have generally understood the need for this delay, there are pressures mounting in the system to resolve the question and handle the variability issue in a consistent manner. As a result, EPA may not have unlimited flexibility in handling this issue.

A third point is that although most of these decisions are related to local scale objectives, there are two exceptions: the potential fine particle NAAQS and the Stack Heights regulation. A secondary, fine particle NAAQS would be based on concerns over region-wide visibility. Since sulfates make up an important fraction of the fine particle mass, it is likely that a fine particle standard would result in controls on sources of SO_x as was

noted in Section II above. In enacting the Stack Heights provisions Congress was concerned that: 1) local air quality goals be met with emission reductions and not dispersion techniques, and 2) regional air quality not be degraded through the use of "tall stacks". Thus the Stack Heights regulation is motivated by both local and regional scale concerns.

A fourth and final point concerning all of the pending SIP and NAAQS related decisions is that no one can be implemented without raising a number of other issues. Specifically, if a SIP emission limit is recalculated for whatever reason (e.g., Stack Heights, Emission Limit Averaging, etc.), current Agency modeling guidance requires that a number of factors be handled quite differently than was the case several years ago. For example, more years of meteorological data are required, the number of model receptors is specified, background levels have changed. These changes generally reflect technical changes in modeling guidance made to improve the accuracy of modeling estimates. This means that, although it is analytically possible to estimate emission changes due to a change in a single policy, in actual practice any one change will unlock the door on a number of other changes as well.

C. Seven Major Decisions: Potential for Moving Targets

As noted above, seven of the pending regulatory/policy decisions are more major in terms of their effect on numbers of sources and emissions. These decisions are listed in Table III.2 along with estimates of their emission reduction potential. EPA possess some discretion on all of these except the Stack Heights regulation. In the Stack Heights regulation the Agency's discretion both with respect to timing and stringency is sharply limited by court decisions. As can be seen the estimated emissions reduction

Table III.1
Integrated Sulfur Strategy
Regulatory Summary

Regulation/Policy	Effective Date	Comment
<u>SIP RELATED</u>		
*1) Stack Heights	1/85	Could result in emission decrease of 0.8 to 2.9 million TPY.
2) Section 126 (Interstate Abatement)	12/84	Denial of petitions results in no emission change; no estimate made of reductions if petitions granted.
3) ICS (Intermittent Control Systems)	Fall 1985	Could affect 2 smelters and only a few other sources; small impact. No quantitative estimate.
4) Visibility Plans	NSR & Monitoring-6/85 Full Plan-2/87	Not expected to have major impact on emissions. No quantitative estimate.
*5) Block vs. Running Average	-	If implemented could be significant; sample plant analyses only.
*6) SIP Emission Limit Averaging	-	Potentially significant; No quantitative analysis available.
<u>NSPS RELATED</u>		
7) Industrial Boiler NSPS	11/86	200-400K TPY, from new sources by 1990.
8) Refinery FCC Regenerator	4/85	70-76K TPY, increasing over time.
9) Onshore Natural Gas Processing	8/85	95K TPY, increasing over time.
*10) Subpart D/30-day average (1971 Utility NSPS)	11/85	Could impact 200 units covered by Subpart D.
*11) Subpart Da (1978 Utility NSPS)	Review	Effect unknown; would effect increases of SO ₂ emissions.

Integrated Sulfur Strategy
Regulatory Summary (continued)

<u>Regulation/Policy</u>	<u>Effective Date</u>	<u>Comment</u>
<u>MODELING RELATED ISSUES</u>		
12) Modeling Guideline	12/85	Minimal impact.
13) Uncertainty in Models		Scope not completely defined. Impacts not quantified. Relates to #6 above.
<u>COMPLIANCE RELATED</u>		
14) CEM (Continuous Emission Monitoring)	FY 85/NSPS	Impact on NSPS units not expected to be great. If expanded to other sources could be substantial. No quantitative estimates. Relates to #6 above.
<u>STANDARD SETTING</u>		
*15) SO ₂ NAAQS Review	7/86	1-hour NAAQS could result in 4-9 million TPY reduction. Reaffirmation would likely result in no change.
*16) PM NAAQS Review	85-87	Fine particle (<2.5 µm) secondary standard could result in minor to major emissions impact depending on level, implementation policy

* Indicates more major policy/regulatory decision

associated with this regulation range from about 1 to 3 million tons per year (TPY). The low end of this range assumes that most affected sources will be able to justify their present stack height, while the upper end assumes most affected sources will be required to make some reduction. More than most of the other regulations the Stack Heights issue illustrates the need to integrate both local and regional scale concerns into a consistent program. As noted previously, one of Congress' principal concerns in enacting this provision was the effect of emissions from tall stacks on regional air quality. However, if a program of emissions reductions to achieve regional air quality goals were implemented, the need for a separate policy on stack heights would largely disappear. Once region-wide emission reductions are achieved the height of individual stacks would become much less important. Moreover, depending on the regional strategy selected, individual sources might be required to make either a greater or lesser emission reduction than under the Stack Heights regulation. This is illustrated in Section V below.

Recently completed impact analyses have shown that this regulation will primarily affect utility power plants, but may also affect other source categories as well (e.g., industrial boilers and Kraft pulp mills). Related analyses have shown significantly greater emission reductions can be obtained for the same cost if a least cost strategy were adopted in place of one based on stack height. The estimated emission reductions shown come exclusively from the utility sector.

The fact that the Stack Heights regulation is likely to have so major an impact (1-3 million TPY) raises a basic and unsettling question regarding the Agency's policy perspective. As noted in the "Introduction", decision-makers have tended in some cases to try to maintain the status quo so as not to confront sources with a series of "moving targets". However, if the

Table III.2
Key Regulatory and Policy Decisions

Action	Emissions Reductions Potential in 1995	Comment
SIP Policy		
1) Stack Heights	1-3 million TPY	Some uncertainty
2) Block vs. Running	~ 0-1 million TPY	Large uncertainty
3) SIP Emission Limit Averaging	0-3 million TPY	Large uncertainty, Emissions could increase
NSPS		
4) Utility Boiler (1971) 30-day average 3-hour average	Minor -	No EPA National Quantitative Analysis
5) Utility Boiler (1978)	-	Analysis not yet initiated
NAAQS		
6) SO ₂ NAAQS: Reaffirmation 1-hour NAAQS	Minor 4-9 million TPY	Depends on SIP policies Some uncertainty
7) Fine Particle	Minor to major	Analysis will begin in '85

status quo is going to be seriously disrupted anyway (assuming the Stack Height provision is not voided by Act amendments), decision makers may wish to maximize other objectives in their remaining decisions. Again, however, whichever perspective is adopted it will be important to understand how the various programs interact.

A number of observations can be made regarding the other six major decisions. The first is that, although in no case has the Agency made a final decision, the most likely options for the three most current decisions (i.e., Block vs. Running Averages, Emission Limit Averaging for Utility NSPS (1971), and SO₂ NAAQS) would cause little or no change from present practice. In these cases, there now appears to be little likelihood that sources will be confronted with "moving targets". In the three remaining cases (SIP Emission Limit Averaging, Utility NSPS (1978), and Fine Particle NAAQS), the Agency is further from selecting an approach, but has some discretion both with respect to the stringency and timing of the regulation. This discretion could be used to coordinate actions and take into account possible regional programs. A cautionary note in this regard is that court suits could take some of this discretion from the Agency. If the Agency's discretion is taken away or if the Agency itself decides on a course which does not emphasize regulatory stability, the potential for confronting sources with a "moving target" is high. Recently completed impact analyses have shown that individual sources can be faced with very different emissions limits depending on the regulatory strategy being considered. This conclusion is supported and illustrated in Section V below.

A second point is that, similar to the Stack Heights regulation, the other six key decisions appear to have their greatest impact on the utility industry. This should not be unexpected since utility emission constitute 67% of total U.S. emission of SO₂. For example, a 1-hour NAAQS would

achieve 77-80% of its emission reductions in the utility sector alone. By definition the two NSPS decisions listed will affect only the utilities. Although detailed analyses have not yet been completed on the remaining actions it is expected that they too would primarily affect the utilities. The fact that the same set of sources is implicated in all of these decisions makes an integrated approach more desirable.

A third point concerns the uncertainty of the estimated impacts. Any national impact analysis of a regulation has some degree of uncertainty in its results. This uncertainty can arise from problems in the data bases used in the analyses, from the analytic techniques used, or from problems in forecasting how a regulation will be implemented. All of these factors enter into the uncertainties noted in Table III.2. Of particular concern is that the impact estimate for "SIP Emission Limit Averaging" is more uncertain than all others. No formal national analysis of this decision has ever been undertaken and the estimate shown was indirectly derived from the SO₂ NAAQS impact analysis.

In addition to the fact that no analysis is available on SIP Emission Limit Averaging, this issue stands out because of its potential to cause large changes in current emissions. Emission limit averaging is a key variable in determining the level of allowable emissions. A consistent, national policy on this one issue, depending on its content, could either result in a sizeable decrease in SO₂ emissions, a maintenance at current levels, or even an increase in SO₂ emissions. The problem at issue here is that since the sulfur content of coal varies, the averaging period used to determine compliance with an emission limit is critical in determining emissions reductions and air quality improvements. A major difficulty with analyzing this issue is that current SIP emission limit averaging and

compliance practices vary so widely from state to state it is difficult to establish a national baseline from which to estimate change. However, SIP revisions received from several key States (Indiana and Pennsylvania) have opened up this issue. Given the potential impact on emissions, this issue should be decided as a national policy matter and not on an ad hoc basis. In this light, further study of this key issue clearly appears warranted.

D. Conclusions

In summary, the review of pending regulatory and policy actions found some 16 actions with a potential for affecting SO₂ emissions. Of these, only seven appear to be major in terms of their effect on emissions. In one case, Stack Heights, the Agency has little discretion on the stringency and timing, while in the remaining six it possesses some discretion. While the Agency can exercise this discretion in ways which emphasize regulatory stability, nonetheless the potential for confronting sources with "moving targets" is high. In all cases it appears that the utility industry would be most affected by the regulations being considered. In the case of SIP Emission Limit Averaging further analysis is needed to determine the potential decreases (or increases) in emissions.

Finally, a review of the current regulatory program indicates that, as presently conceived, local scale programs will not result in emission reductions of the same order of magnitude as those contemplated in many of the potential regional programs (i.e., several million tons). Since the current ambient standards are met in most areas and the overwhelming majority of sources are in compliance, the emissions reductions which can be expected are small. This implies that, absent major policy shifts, current programs will not provide the reductions being discussed in many of the regional program proposals. However, a number of the policy/regulatory decisions now

pending (e.g., Stack Heights, 1-hour SO₂ NAAQS, Utility NSPS, and SIP Emission Limit Averaging) have the potential of reducing SO₂ emissions by several million tons or more . As noted, many of the strongest options being considered in all but one of the decisions also result in regulatory stability and hence no change in emissions. In the case of Stack Heights, however, where EPA has little discretion, there is a very real possibility that emissions may be reduced by 1-3 million tons per year. This means that major changes in current SIP emission limits are possible and that the status quo may well be disrupted.

IV. An Analytic Review

A. Analyses Underway: What We Have and Have Not Learned

As a result of the heightened concern over acid deposition, the Agency has undertaken a wide range of studies and analyses related to sulfur oxides. In addition, it has also increasingly conducted in-depth impact analyses of all major regulatory decisions such as the SO₂ NAAQS and Stack Heights. Consequently, there are at this time a number of analyses related to SO_x either just completed or nearing completion. This section attempts to catalogue these analyses and presents some observations concerning them.

Table IV.1 presents the major SO_x related studies underway; divided into those addressing local-scale problems and those addressing regional scale problems. A review of the studies permits several general observations. The first is that the studies address a wide range of sulfur oxides related problems and reflect a high degree of analytic sophistication. There are, of course, major uncertainties inherent in the results coming from all of these studies. Nonetheless, they have added considerably to our understanding of how various strategies affect emissions, costs, and benefits. Secondary impacts, such as differential effects on coal production and mining employment, have also been studied. There is now a sizable body of data concerning the way in which various strategies might be implemented and the environmental results which might be anticipated. There are models available to forecast emissions and costs and other models to predict air quality impacts on a regional scale. It must be recognized that these models are uncertain. Nonetheless, they do provide a means by which relative comparisons of very different policies can be made.

Table IV.1

Quantitative Analyses of Alternative Sulfur Oxides Policies

Study	Completion Date	Sponsoring Office	Comment
<u>Local Scale</u>			
1) SO ₂ NAAQS RIA	9/84	OAQPS	Addresses national impact of 1-hour NAAQS examines related regional-scale impacts
2) Block/Running Average	12/84	OAQPS	Study of sample plants only, no national or regional scale impacts
3) Stack Heights	10/84	OAQPS	Addresses national impact of Stack Heights reg., no regional-scale impacts examined
<u>Regional Scale</u>			
1) Acid Deposition Implementation Issues	11/84	OAQPS	Analysis of issues to be addressed in implementing regional programs
2) Assessment of Eastern Regional SO _x Strategies	12/84	UPPE	Analysis of a range of regional scale strategies and impacts, no analysis of local goals and constraints
3) Western Visibility Analysis	12/84	UPPE	Analysis of Western visibility, no analysis of local goals
4) DOE Long-Term Emissions Strategies	1/85	DOE	Emissions and cost study only
5) Integrated Acid Deposition Assessment	2/85	OAR	Assessment of current damages from acid deposition
6) Visibility Task Force Report	2/85	OAQPS	Will make recommendations regarding regional visibility
7) Improvement to Regional Transport Models	87	ORR	Longer term effort leading to Eulerian model
8) Acid Deposition Assessment	87	OAR	Impact assessment of alternative acid deposition policies
9) Completion of AUSA	-	ORR/ OAR	Longer term effort to bring utility/coal market model on-line

At present many of the analyses shown in Table IV.1 have only just been completed and are undergoing review. In some cases sensitivity analyses have been undertaken. Therefore it is too early, and in any case beyond the scope of this paper, to summarize all of the findings of the studies. It is planned that the more significant results be drawn into a briefing for Agency management in the near future. The remaining observations presented here focus on general concerns.

The second observation is that none of the current studies were designed to take a systematic look at all aspects of the sulfur oxides problem. Generally, the studies focus on environmental effects or regulatory programs on only one geographic scale. For example, the Stack Heights analysis examined the national emissions and cost implications of compliance with the revised Stack Heights regulation. No analysis was made of the impact the estimated emission reductions might have on the various regional scale air quality indicators. Neither was any comparison made of the sources which would be controlled under this regulation and those controlled under other possible strategies (e.g., 1-hour SO_2 NAAQS). The examination of single objectives does provide decision makers with useful information. However, the fact that the same set of sources is likely to be affected by all of these regulations argues that a more integrated analysis be undertaken as well.

A third observation is that, although most of the studies have focused on single objectives as noted above, analytic techniques are being developed to examine multiple effects. In some of the more recent studies, this capability to examine multiple effects has been exercised. For example, the Assessment of Eastern Regional SO_x Strategies examined the impact a variety of regional reduction strategies would have on a number of different

environmental indicators (e.g., visual range, sulfate levels, deposition). In another study, the SO₂ Regulatory Impact Assessment, the effect of several local-scale strategies on the same set of regional-scale environmental indicators was studied.

A final observation is that at least one critical policy question is not addressed at all by these studies: SIP Emission Limit Averaging. Indirect assessments of this question have all shown that a consistent approach to emission limits could have a significant impact on total emissions. However, it would be extremely difficult to complete a national analysis of this problem because the baseline (i.e., current practice) from which to measure change varies so widely from state to state.

B. Models and Data: The Analytic Underpinnings

In addition to the foregoing observations on the analyses and studies, there are several observations which can be made regarding the data bases and models which are common to most if not all of the studies. Fundamental to all of the analyses is an emissions inventory. As was noted in the preceding section, the utility sector is the most important component of the inventory (67% of total emissions). One significant contribution of the National Acid Precipitation Assessment Program (NAPAP) has been the development of a national inventory. This inventory was developed for use in regional analyses and in the opinion of most analysts is adequate for that purpose. However, most local-scale strategy analyses of the utility sector require more detailed information on the stack parameters and operating characteristics of individual units. A number of analysts working on local-scale studies have encountered significant problems in using the utility sector portion of the NAPAP inventory. Missing or inaccurate stack data appear to be the most frequently encountered problems.

NAPAP and the National Air Data Branch of OAQPS have agreed in principle to jointly develop and maintain, on the EPA computer, a utility reference data system. This would incorporate the best available information from several sources in one control data base which would support NAPAP emissions inventory and modeling work as well as other users. As more detailed or improved information is developed in specific applications, it should be automatically incorporated into this system. In this way, the best current information at any given time will be available to all users. This plan should be funded and implemented, with the full cooperation of all Agency users of utility data.

It is also important that the NAPAP data base maintain a time dimension. It now appears likely that sulfur oxides will continue to be a concern of EPA for some years to come. In such an event, data measuring trends in emissions and resultant changes in environmental indicators will be extremely important. A recent (1973-82) historic data base is currently maintained by NAPAP for utility point sources, and will be incorporated into the reference data system. A commitment to updating this record annually as new data is available, and maintaining a historic record should remain a high priority of NAPAP and the Agency. This updating should make maximum use of the information collected on the Department of Energy's Forms 759, 423, and 767 all of which are available on an annual or monthly basis. Additionally, the entire NAPAP point source inventory for SO₂, including non-utility sources, should be updated periodically, annually if possible.

A third observation concerns the model(s) used to forecast emissions and costs under alternative strategies. In recent years, EPA studies have relied on one model: ICE's Coal and Electric Utilities Model (CEUM). CEUM is now generally accepted by all parties to the sulfur oxides discussion as the state of the art model despite some reservations. Analysts within and outside

the Agency had suggested a number of areas in which improving the state of the art in utility modeling would be desirable. These include (1) modeling of the interaction of control costs, revenue requirements, rate changes and demand for electricity, (2) treatment of the financial impacts of control strategies on utility companies, (3) improved efficiency and accessibility to government analysts, etc.. A major research project has been sponsored by EPA to develop a new model, the Advanced Utility Simulation Model (AUSM), which includes improvements in some of these areas. The development effort is largely complete and extensive testing is scheduled over the next several months. Upon completion of a testing and evaluation period, the model will become publicly available. It is important that the testing process be conducted thoroughly and carefully, that any deficiencies discovered be corrected or fully documented, and that the model enter the public domain in a controlled manner with all appropriate caveats.

In summary, EPA has sponsored a wide range of studies and analyses of the various aspects of the sulfur oxides problem. Extensive data bases and sophisticated models have been developed. Taken together all of these activities have contributed significantly to our understanding. However, there are still some gaps and deficiencies. An important deficiency is that most of the studies have examined only one objective and one strategy. At least one critical policy question, SIP Emission Limit Averaging, has not been addressed. Finally, there are deficiencies in the inventories being used and heavy reliance is being placed on one key model (CEUM) to forecast emissions. Nonetheless, many of the analytic elements needed to design an integrated strategy are already available.

V. An Analytic Framework for An Integrated Strategy

A. A Sample Strategic Matrix

This section provides the outline of an analytic framework for comparing different sulfur strategies. This framework could also be used to derive new, integrated strategies (i.e., strategies which meet multiple objectives on both geographic scales). One of the principal concerns motivating this conceptual study was the possibility that sources might be faced with a succession of SO₂ emission limits each imposed for a different policy objective. As was seen in Section III, there is a real potential for confronting sources with "moving targets." Moreover, it was also shown that the utility industry would be most affected. In Section IV it was shown that most analyses have focused on only one geographic scale and only recently has the capability to examine multiple effects been exercised. As a result, some understanding has been built of the effect of regional scale and some local scale strategies on regional scale effects. However, scant attention has been paid to local scale goals and constraints in regional strategy design. In addition, analyses of local scale strategies have tended to examine only one objective at a time.

The ability to derive integrated strategies, strategies which consider multiple objectives on both scales, will depend in large part on the development of an analytic capability to simultaneously handle both local and regional scale impact considerations. The full development of such a capability was beyond the scope of this initial conceptual study. However, as a first step in the development process, and building on analyses completed for other purposes, a sample matrix to compare strategies was developed and is shown in Table V.1. The matrix shows the expected emission rates for ten utility power plants under each of six strategies plus two different

Table V.1
Sample Sulfur Strategy Matrix
Estimated 1995 Emission Rates¹
(lbs SO₂/MM Btu)

Plant/Unit	(MM)	Current	1995 Basecase	1-hour 0.5 ppm MAAQs	1-hour 0.25 ppm MAAQs	Stack Heights High Impact	SIP Emission Limit Averaging	Waxman- Sikorski C/E	Waxman- Sikorski Equivalent	12-Million TPY	31-State
Devon #1	(100)	0.43	1.39	1.39	1.37	N/A	-	1.37	1.37	0.9	0.9
Portland #2	(246)	3.13	3.14	3.10	1.51	N/A	-	3.14	2.89	*0.26	*0.26
Amos #3	(1300)	1.26	1.33	1.33	1.05	N/A	-	1.33	1.33	*0.17	*0.17
Fort Meyers #1	(154)	2.41	2.65	2.54	2.23	N/A	-	2.54	1.00	*0.10	*0.10
Gavin #1	(1000)	5.47	6.08	6.19	2.54	1.53	-	*0.50	2.73	*0.62	*0.62
Brown #1	(250)	0.81	0.96	0.96	0.96	N/A	-	0.96	0.96	0.96	0.96
Tanners Creek #4	(525)	8.09	6.88	4.22	2.28	N/A	-	*0.67	2.40	*0.33	*0.33
Waitegan #8	(358)	0.97	1.50	1.42	1.01	N/A	-	1.50	0.94	1.02	1.02
Miller #1	(662)	1.03	1.01	1.01	1.01	*0.51	-	0.68	0.99	*0.69	*0.69
Sioux #2	(452)	4.66	4.00	2.22	*0.64	N/A	-	*0.67	2.08	*0.67	*0.67

¹The estimated 1995 emission rates include reductions due to the strategy being considered and also the effect of changes in the market price of coal due to demand changes.

*Indicates scrubber retrofit.

baselines (1980 and 1995). Before discussing this sample matrix two cautionary thoughts are in order. The first is that the use of national impact studies to predict plant level changes is highly uncertain. The estimated emission rates shown in the matrix are drawn from studies performed using a least cost model of the coal and electric utility industries (ICF's CEUM model). Such models are more reliable when used for national or regional level predictions. Secondly, it should be noted that the emission rates shown in the matrix reflect not only the direct effects of the strategy being considered, but also the effect of changes in the market price of coal due to demand changes. As a result the emission rates shown could be lower than the rate or limit required by the strategy. With these cautions in mind, it is still useful to begin comparing plant level effects in order to fully understand the impact of various strategies and to begin to see how an integrated strategy might be derived.

In Table V.1 the current emission rates and the estimated 1995 base case emission rates are shown for each of ten plants. The estimated emissions under three local scale strategies (1-hour NAAQS of 0.5 ppm and 0.25 ppm, and the Stack Heights regulation, as well as three regional strategies (Waxman-Sikorski, a cost effective equivalent to Waxman Sikorski, and a 12-million ton reduction strategy) are also shown. A review of the matrix allows two basic observations to be made:

- 1) Strategies Have Large Differential Impacts: It is probably obvious that strategies which result in very different national emission reductions will most likely also have very different source level impacts as well. However, strategies which have approximately the same national reductions can also produce very different source level impacts. For example, in Table V.1 Portland Unit #2 would need to

cut its emissions in half to meet a 0.25 ppm 1-hour NAAQS (9 million ton strategy), would be untouched by Waxman Sikorski (also 9 million ton strategy), and would make only a small reduction under the cost effective equivalent (also 9 million ton). An opposite effect is seen in the case of Gavin Unit #1. For this plant a 0.25 ppm 1-hour NAAQS would require a major reduction, but it would be forced by Waxman-Sikorski to scrub and reduce its emissions by an order of magnitude. In a third case, Miller Unit #1, the Stack Heights regulation (2.8 million ton national reduction) would require a greater reduction than the 12-million ton 31 state strategy. Comparisons of this type lead to the strong conclusion that the design of a regulatory strategy can have a very large differential impact on individual sources even when the national emissions reduction figures are comparable. The design of strategies can also have very large differential macro-scale impacts as well. For example, some of the recent studies discussed in Section IV above, have shown significant shifts in coal production and mining employment.

2) Regional Strategies May Not Meet Local Goals: A common perception is that large regional reduction strategies will always dominate strategies based on local concerns. In most instances this is true and becomes increasingly true as the size of the regional reduction increases. Nonetheless, as a review of Table V.1 shows it is not always true. At the Waukegan Unit #8, for example, neither of the two possible alternative one-hour air quality goals would be met by Waxman-Sikorski. If both the 0.25 ppm 1-hour alternative NAAQS and Waxman-Sikorski became Agency goals, then half of the plants in this sample would

require additional control to meet the local goal not needed for the regional goal.

This limited comparison focused on only the ten power plants and seven strategies shown and used emission rates as the only criteria for comparison. Nonetheless, even this limited comparison illustrates the importance of considering all goals and objectives in evaluating possible SO_x regulatory strategies. The possibility of large differential impacts and the potential for not meeting important local goals both argue for an integrated approach. A review of the sample matrix also suggests that it may be possible to devise an integrated strategy from the bottom-up. One could for example specify the local goals to meet, a regional emissions reduction target, and then by analysis of the matrix put together individual source reductions in an integrated strategy. This approach would allow consideration of multiple goals on both scales. However, to begin to derive alternative, integrated strategies the sample matrix shown here would need to be expanded and improved.

B. Suggested Improvements

Clearly to consider national strategies, the sample matrix would need to be expanded to include most, if not all, major utility power plants. In addition, other strategies (e.g., 10- and 12-State strategies, cost-effective equivalent to Stack Heights) should also be added. Finally, other criteria for comparing the plant level impacts of the various strategies should be added. Although emission rates are very useful for comparison purposes, other measures would help to fill in the picture. For example, total fuel consumption at a plant would indicate the dispatch of that plant. The change in annual and capital cost measured from the 1995 baseline would also be useful. Other measures of impact might include total annual emissions and controls (e.g., scrubbing, coal washing, fuel switching,

etc.). Information on plant level constraints could also be added (e.g., Is the plant scrubber capable? Is it a mine-mouth plant "locked into" its coal supply?). The expansion of the matrix in the three dimensions noted above (sources, strategies, and impact measures) would, however, involve a volume of data which would preclude simple hand tabulation. There are readily available computer data base programs to store and manipulate matrices such as the one contemplated here.

The expansion of this matrix framework and its conversion to a computer format would permit easier analysis of strategies. One could readily compare the impact of different strategies; determining for example the extent to which local goals are met by regional strategies. The problems local constraints might pose in regional strategy implementation could be more accurately assessed. In addition, an easily accessible data base such as this would make it possible to fit individual SIP actions into a larger context. When, for example, a change to a source's SIP limit is requested, it would be possible to determine how that revised limit compared to limits being contemplated under alternative strategies.

The expanded matrix would also represent an important first step in developing the capability to design integrated strategies. As noted above, once multiple local and regional scale objectives were specified, an analysis of the matrix could point toward the individual source reductions which would make up an integrated strategy to meet those goals. However, it should be stressed that there are limits on the usefulness of such a matrix in the design of an integrated strategy. Although the matrix is an important first step, it would still be necessary to analyze any strategy being considered using a utility/coal market model (e.g., ICF's CEUM model or EPA's AUSM). This would be necessary because the emission rates and reductions stored in

the matrix for any given strategy are a function of not only the limits imposed by that strategy but also the market adjustments resulting from the ensemble of individual source limits. Moreover, in designing integrated strategies it will be necessary to assess how each strategy affects the various criteria listed in Table II.1. Other macro-scale impacts would also need to be examined. As noted earlier, different strategies can have very large differential impacts on coal mining production and employment. Even with these limitations, the development of an expanded source matrix is an important step in improving the Agency's ability to derive integrated strategies. Although the development of the matrix would facilitate the design of integrated strategies institutional constraints might preclude their being proposed. In this event the matrix would still be an extremely useful tool in providing better coordination of the pending local scale decisions.

VI. Conclusions and Recommendations

As noted at the outset of this paper, this study was designed to assess the possibility of an integrated sulfur oxides management strategy. As a result of the study it is possible to state a number of preliminary findings and make recommendations for further work.

A. Conclusions

The preliminary conclusions or findings can be stated as follows: High Potential for "Moving Targets." The review of currently pending policy and regulatory decisions indicates a high potential for confronting the utility industry, as well as other major SO₂ emitters, with a series of moving targets. There is a wide range of decisions pending, each being pursued independently and involving different objectives. Although the Agency has some discretion in all but one of these decisions and can exercise it in ways to emphasize regulatory stability, nonetheless the potential exists for confronting the same set of sources with a series of different emission limits for different policy objectives. The Stack Heights regulation is the one exception where the Agency has little discretion and this regulation results in estimated emission reductions of from 1 to 3 million tons per year. This regulation when implemented now appears likely to result in major changes from the status quo.

Present Local Scale Programs May Not Meet Regional Objectives. It is impossible to state with any certainty whether or not currently authorized local scale programs meet regional objectives since there are no agreed upon regional objectives. However, recent policy and Congressional discussions of possible regional programs have focused on objectives involving emission reductions of at least several million tons. As

presently conceived local programs do not hold the potential for such reductions. However, the Stack Heights regulation, as proposed does hold the potential for such reductions. Moreover, several of the pending decisions regarding other local scale objectives (e.g., 1-hour SO₂ NAAQS, Utility NSPS, and SIP Emission Limit Averaging) could also result in emission changes exceeding several million tons.

Two Policy Perspectives. Two different policy perspectives have frequently been adopted in discussions regarding sulfur oxides. One holds that the status quo should be maintained where possible until regional objectives and programs are agreed upon. The second holds that since a regional emissions reduction strategy may be coming, pending decisions should be made to obtain incremental progress towards eventual regional goals. The possibility that the Stack Heights regulation, over which EPA has little discretion, will cause a major change in current emissions should cause a reconsideration of the validity of the first perspective in all remaining decisions.

Effects of Regional Programs on Local Objectives Not Understood. Most recent analyses of possible regional-scale emission reductions have focused on how such reductions might effect regional criteria (e.g., SO₄ concentrations, visibility, deposition). In addition, recent studies of local scale programs have also examined effects on regional criteria. However, little attention has been paid to the question of how all programs might affect a range of local scale objectives and constraints. It is not surprising that regional studies have focused on effects on that scale. It is somewhat less expected that studies of local scale programs have focused on single objectives and largely ignored all others. As a result there is a lack of understanding as

to how a range of local scale objectives and constraints may be affected by the programs being considered.

Integrated Strategies Are Possible. Although there are gaps in the data and analytic capability needed to devise integrated strategies, it appears possible with some additional work to devise such strategies. Detailed comparisons of the control requirements and objectives of different strategies will permit the design of more integrated strategies to maximize multiple objectives. A better understanding of the dimensions and impacts of key local scale decisions (e.g., SIP Emission Limit Averaging) is clearly needed. In addition, a framework for considering impacts on both geographic scales is needed. Given these developments it will be possible to devise integrated strategies. Moreover, these developments would permit better coordination of pending policy and regulatory decisions even if institutional or other constraints precluded the proposal of an integrated program. An important corollary to this conclusion is that, in addition to better analyses, the present management system should be examined for possible changes to foster an integrated (or coordinated) consideration of strategies. It is difficult for decision-makers to adopt a systematic approach when parts of a single large problem are given to them piecemeal with little information as to how the parts relate.

B. Specific Recommendations

The results of this preliminary conceptual study have led to the conclusion that the study should be continued. The Office of Air and Radiation has decided to continue the study and set out several objectives to be pursued. A first objective will be the development of a source/strategy matrix for comparing strategies and beginning the development of integrated strategies.

Much of the data to fill in an expanded matrix have already been developed in the course of other studies. Pursuit of this objective will involve the preparation of data for this use and the development of computer programs to store and analyze the data. Work on this objective has already been initiated within OAR.

The second objective would be to fill in the gaps in our understanding of key local scale decisions. Critical in this regard is the SIP Emission Limit Averaging question. Fundamentally, this question concerns the way in which the Agency will handle the sulfur variability problem and in an even larger sense the way in which it will handle uncertainty. A study to determine the impact a consistent national policy on emission limit averaging and compliance would have is being considered and funding sought. The results of such a study would help to inform decisions on range of policy questions as well as the SIP Emission Limit Averaging question.

This initial conceptual effort also identified two additional areas for further work that are beyond the scope of this study. Specifically, it was found that the Agency's present utility data base is inadequate in two respects. In the first place, although the present utility inventory is adequate for regional policy studies, its usefulness for local scale studies is limited due to inaccurate or missing data. Secondly, since it appears likely that the Agency will be considering these issues for some time, it is important that a time dimension be added to the inventory. Therefore, a program should be considered to fill in the gaps and correct errors in the present file, and to update and maintain the files over time.

The second related area involves the Agency's ability to forecast emissions in the future. Presently ICF's CEUM model is used for this purpose and is generally accepted, despite some reservations, by all parties

to the sulfur strategy discussions. The Agency has made a considerable investment in a new model, AUSM, which is believed to resolve some of the problems identified with CEUM. This conceptual study would indicate that it is important that AUSM be reviewed, tested, and, if warranted, used in an operational mode to assess policy options. A program involving the Office of Research and Development (ORD), the Office of Air and Radiation (OAR), and the Office of Policy, Planning, and Evaluation (OPPE) is being elaborated to accomplish this and should be supported.

APPENDIX

A REGULATORY CATALOGUE

I. Stack Heights Regulation

Section 123 requires the Administrator to promulgate regulations to insure that "the degree of emission limitation required for the control of any air pollutant..." is not affected by stack height for any source which exceeds "good engineering practice" (GEP) or by any other dispersion technique. The promulgation of these revisions to regulations is expected to modify the degree to which emission sources are permitted to take credit for the dispersive limitations. This, in turn, will affect the level of emissions control required of the sources before receiving operating permits.

II. Schedule

Proposal	11/84
Promulgation	1/85
Revise SIP submittals	10/85

III. Need for Action

Regulations previously developed to carry out this requirement were overturned by the U.S. Court of Appeals for the D.C. Circuit and a mandate was issued on July 18, 1984 requiring the promulgation of revised regulations by January 18, 1985.

IV. Key Issues

The key issues in this regulatory package concern how EPA defines certain terms in the regulation:

There are two ways of attaining the NAAQS: emission controls and dispersion techniques. Constant emission controls involves the use of technologies or limits that prevent pollutants from being generated or that remove pollutants from waste gas on a continuous basis. Dispersion techniques spread the emissions over a wider geographic area either by releasing the pollutant at a higher elevation (tall stack) or by varying the rate of emissions according to atmospheric conditions. Dispersion techniques have been used to meet the SO₂ standard more than to meet any other standard. Thus, they have contributed to the total atmospheric load of sulfur.

The key issues in the revision to the regulations involve: redefining several important terms including "dispersion techniques" and "excessive concentration," determining the amount of credit which a source may have to avoid downwash created by terrain obstacles, and determining what is an acceptable dispersion technique.

V. Nature of Impacts

It is estimated that this regulation could reduce emissions by 1 to 3 million tons per year depending on the number of affected sources which can justify their present stack height. Annual costs ranged

from \$300 million to \$1,400 million. The effects will result from having to conduct additional demonstrations to justify stack heights, and from the reduction in stack height credits below what was previously allowed, consideration of terrain effects over long distances in fluid modeling studies, or use of previously permissible dispersion techniques. This reduction in credit may require more stringent emission limitations on many affected sources which will have to be met through the substitution of cleaner fuels or the application of additional control equipment. Affected sources include powerplants, industrial boilers, smelters and pulp and paper mills throughout the country.

I. Section 126 Determinations

The Agency has proposed to deny the petitions filed in 1980 and 1981 by Pennsylvania, New York, and Maine. These petitions alleged that midwestern States emit SO₂ which causes: 1. the SO₂ NAAQS to be violated and the SO₂ PSD increments to be interfered with in western Pennsylvania; 2. the formation of sulfates which in turn causes acid rain, TSP NAAQS violations, TSP PSD increment consumption, and visibility impairment.

II. Schedule

Proposed Determination	9/84
Final Determination	12/84

III. Need for Action

Section 126 requires a determination to be made within 60 days of receipt of a petition, as noted above, the petitions were filed in 1980 and 1981. In March 1984, the petitioning States filed suit against EPA to bring about a decision, the Court issued a decision in October 1984 requiring EPA publish its final determination by December 4th.

IV. Key Issues

The allegations raised by the petitioning States are:

1. Sources in Ohio and West Virginia emit SO₂ which is transported into western Pennsylvania causing violations of the SO₂ NAAQS and interference with Pennsylvania's PSD SO₂ program.
2. Sources in seven midwestern States emit particulates and SO₂ which transforms into particulate sulfates which are transported to the petitioning States causing acid rain, violations of the TSP NAAQS, consumption of the TSP PSD increment and visibility impairment.

A number of important issues are addressed in the determination, including:

- 1.. Section 126 applies only to criteria pollutants and pollutants for which there are PSD increments, not to acid rain and sulfates per se. Sulfates can be addressed as TSP however.
2. Section 126 does not apply to the "regional haze" form of visibility impairment since that type of impairment cannot

be traced directly back to a source through visual techniques.
3. Section 126 may be applied to the cumulative effect of many sources rather than to the effect of a single source.

The record developed for the petitions did not support a finding that the midwestern States were causing or significantly contributing to a violation of a NAAQS, nor did the record show that those sources were interfering with the petitioning State's visibility programs.

V. Nature of Impacts

Denial of the petition will allow individual States to maintain the status quo, sources in the States alleged to be causing problems will remain subject to current SIP requirements, rather than having to meet more stringent emission levels which would result if the petitions were granted.

I. Intermittent Control Systems (ICS) Regulation

Section 123 of the Clean Air Act prohibits the use of dispersion techniques for meeting the national ambient air quality standards and other provisions of the Act. It only exempts from this prohibition those stack height that were "in existence" and those other dispersion techniques that were "implemented" as of December 31, 1970. The Agency, under Section 123 of the Clean Air Act (CAA), must propose rules that define "implemented" dispersion techniques before such can be used in a State implementation plan (SIP). Since the major dispersion technique other than tall stacks is the use of ICS, this rulemaking defines the necessary components of implemented ICS and sets forth basic guidance on incorporating ICS into a SIP.

II. Schedule

Proposal	9/84
Promulgation	9/85

III. Need for Action

This rulemaking will complete action under Section 123 of the CAA by addressing the allowance of this dispersion technique in SIP's. There are two sources: ASARCO in Tacoma, Washington, and ASARCO in El Paso, Texas, that have stayed court actions on the SIP emission limits pending EPA action on these rules.

IV. Key Issues

The key issues are what a source must show in order to obtain credit for an ICS and what a State must require of the source in order for that credit to be allowed in the SIP. The present package includes required components of an ICS and restrictions that should be included in the SIP. These directly affect the number of sources that could use an ICS in place of constant SO₂ emission controls.

V. Nature of Impacts

This action will affect very few sources, since most have installed constant emission controls or do not qualify as having a fully implemented ICS as of December 31, 1970. However, as previously mentioned, two major smelters and perhaps a few more sources will have sufficient economic motivation to pursue credit under this rule. For those sources, the ability to continue operation of an ICS may be important. Since they are major SO₂ emitters, this rule will affect total SO₂ loadings to some extent.

I. Visibility Federal Implementation Plans

The Agency is required to propose and promulgate implementation plans for States with mandatory Federal Class I areas that do not have approved visibility protection State Implementation Plans (SIP). The Agency will phase its action by promulgating the new source review (NSR) and monitoring strategy requirements first. This will be followed by the remaining portions of the rule, which include, integral vista protection, long term strategy to meet the visibility protection goal and examinations of existing major sources that are creating visibility impairment problems. These rules only address visibility impairment reasonably attributable to a single source or group of sources such as a specific plume, or a valley-fill situation. Action on regional visibility impairment will be addressed by future Agency action.

II. Schedule	<u>Plans for NSR & Monitoring</u>	<u>Remaining Portions</u>
Proposal	10/84	6/86
Promulgation	6/85	2/87

III. Need for Action

The Environmental Defense Fund, et al. sued the Agency for failing to promulgate plans for the 35 deficient States. A settlement agreement was negotiated and signed by the court on April 20, 1984. The agreement calls for proposal and promulgation of the monitoring strategies in approximately 14 months, followed by the remaining parts of the rule over the next 14 months. The agreement allows EPA to delay either promulgation for up to 6 months if a State submits its own plan to meet the requirements.

IV. Key Issue

The key issue in the implementation of plans for the existing regulation that pertains to SO_2 control lies in the approach taken in monitoring. The monitoring systems that are set up under this rule will assess background levels of visibility impairment that could also be used for identifying and evaluating regional haze. Therefore, the selection of monitoring techniques and sites could provide useful data for future programs.

V. Nature of Impacts

In general, sulfur emissions do not cause specific plume visibility impairment since most sulfur is emitted in the form of SO_2 , a colorless gas. However, SO_2 transforms to particulate sulfates which impair visibility by creating a regional haze. Only in a few isolated cases can that sulfate haze be reasonably attributed to a source or small group of sources, i.e. a stagnant air mass which traps the SO_2 in a valley, which is referred to

as a valley-fill situation. Therefore, the implementation of the existing regulations will result in few, if any, controls on SO₂ emissions.

The program will provide information on background visibility conditions and on specific impairment from a source or group of sources and will begin in FY 86. The information can provide a basis for development of a regional haze program which could require controls on some SO₂ sources.

I. Block vs. Running Averages

Ambient monitoring data and modeling predictions regarding the 24-hour primary SO₂ standard and the 3-hour secondary standard have generally been based on block averages (i.e., 12:00 midnight to 12:00 midnight for the 24-hour standard and 12:00 a.m. to 3:00 a.m., 3:00 a.m. to 6:00 a.m., etc., for the 3-hour standard) although neither the block nor running averaging method is specified in the national ambient air quality standards (NAAQS). The EPA could require running averages (e.g., for the 3-hour standard, 12:00 a.m. to 3:00 a.m., 1:00 a.m. to 4:00 a.m., etc.) to be used for monitoring and modeling activities, and the requirement could be implemented through various mechanisms.

II. Schedule

Given, there is not yet an Agency decision on this issue, no schedule has been set. However, if there is to be a decision to specify either running averages or block averages, the Agency may decide to coordinate the schedule with the SO₂ NAAQS revision package.

III. Need for Action

There has been inconsistency in State and EPA monitoring and modeling activities with regard to the use of block and running averages. Several State implementation plan (SIP) revisions submitted to EPA (e.g., Muskingum River) have highlighted the different emission limits required between modeling with block and running averages. The EPA is currently under remand to review monitoring and data reporting regulations that pertain to averaging method although there is not necessarily a court directive to go to running averages for monitoring. The existing NAAQS does not specify either block or running averages.

IV. Key Issue(s)

One of the key issues is whether the block averaging method provides the level of protection envisioned in the SO₂ 24-hour and 3-hour ambient standards. If the Agency decides to specify running, several issues arise with regard to implementing the change: Should all SIP emission limits be revised using running averages in the modeling analysis or should running averages just apply to future SIP revisions? Could EPA be forced to reconsider all sources even if it chose to apply running averages just to future SIP revisions? Should the ambient standards themselves specify running averages or should EPA policy or guidance be the mechanism to implement the change? What should the timing of the specification be in light of other possible changes in SO₂ control (e.g., stack height regulation, acid rain legislation, etc.)?

V. Nature of Impacts

The change to running averages could affect only sources included in future SIP revisions, or it could require a major revisitation of existing SO₂ SIP limits, depending on whether the change is implemented prospectively or in a manner to cover all sources. A major revisitation might not only result in additional control requirements for many sources, but it would also impose a burden on State and EPA resources to modify modeling procedures and review and/or redo previous modeling analyses.

Sources with emissions at levels which just meet the ambient standards based on block averages would most likely show exceedances with an analysis using running averages. Sources emitting at levels which correspond to predicted concentrations below the standards may have sufficient margin to accommodate an increase resulting from running averages. Modeling analyses would be required to determine this.

Monitoring data indicate that block averages may result in SO₂ concentrations that are on the average about 16 percent lower than concentrations based on running averages although the site-specific differences may range from 0-50 percent. Around utilities and other large point sources, the reductions may be larger and in some cases as high as 50%. If modeling data vary similarly to monitoring data, sources that are not at least 16 percent below the standards would likely have to lower their emissions (through control equipment, fuel switching, etc.). An informal review of recent SO₂ SIP revisions submitted to EPA (as of April 1984) indicates that the emission limits for about a third of the sources were set just at the level to protect the ambient standard so that running averages would probably result in exceedances for some of these sources. In addition, in the State of Ohio the SO₂ emission limits were set for each source at levels that would just protect the ambient standards.

I. SIP Emission Limit Averaging

A number of states have submitted SIP revisions which either are whole or in part rely on 30-day average SIP emission limits. The issue of the averaging period contained in an emission limit is critical because the averaging period determines the amount of control needed and the level of resultant air quality. At present, there is a wide range of emission limit averaging practices. Current practices range from short-term limits (3 to 24 hour) up to annual average.

II. Schedule

No formal schedule has been established.

III. Need for Action

EPA proposed to approve a Pennsylvania plan revision of this type in September 1981. It also has received a plan containing a 30-day average compliance provision from Indiana. Although final action has been delayed on the Pennsylvania plan, Section 110 mandates that EPA either approve or disapprove all revisions.

IV. Key Issue(s)

The key issue here is the length of the emission limit averaging period needed to protect the NAAQS (usually the 24-hour primary or the 3-hour secondary). The inherent variability of sulfur in coal coupled with the current deterministic form of the NAAQS makes it difficult to demonstrate that longer term limits will in fact always protect the NAAQS. As noted above, there is a wide range of averaging periods used in current regulations. In addition, even where a short averaging period is stated or implied, sources sometimes comply on a longer term (30-day) basis.

V. Nature of Impacts

A national analysis of the impacts which a consistent national policy might have has not been performed. An indirect estimate derived from the SO₂ Regulatory Impact Analysis showed that a uniform national policy requiring short term limits might cause a reduction of as much as 3 million tons per year (TPY). However, depending on its content such a policy might also maintain current emission levels or even result in an emissions increase. Absent a direct study of this issue, all impact estimates should be regarded as highly uncertain.

I. Industrial Boiler NSPS for SO₂

This rule will affect new, modified, or reconstructed industrial, commercial, and institutional boilers larger than 100 million BTU/hr. Industrial boilers are one of the 56 source categories on the NSPS priority list.

II. Schedule:

Proposal 11/85

Promulgation 1/87

III. Need for Action:

Section 111 of the Clean Air Act requires that NSPS be promulgated for all source categories on the priority list by August 1982. The project is tracked in ATS.

IV. Key Issues:

The Clean Air Act mandates that NSPS for fossil-fuel fired industrial boilers include a requirement for a percentage reduction in uncontrolled emissions if the cost, environmental, and energy impacts are reasonable. The primary issue will be how to include percent reduction requirements in the NSPS. Percent reduction standards for SO₂, in effect, require the use of flue gas desulfurization (FGD) systems, whereas standards with emission limits permit the flexibility for boiler operators to select FGD, low sulfur fuels, or a combination of the two. Percent reduction standards for SO₂ generally are unpopular because FGD imposes higher capital and operating costs, produces a solid waste disposal problem, and discourages the use of coal in favor of oil or natural gas. Percent reduction standards are favored by eastern coal producers because they encourage the use of locally available coals and limit the penetration of western low sulfur coal into eastern markets. While the local coal issue was the major motivation behind the percent reduction requirement in the 1977 Act, industrial boilers have little impact on national coal markets.

V. Nature of Impacts:

The industrial boiler NSPS will reduce SO₂ emissions by between 200 and 400 thousand tons/year in 1990 depending on the amount of future coal use in industrial boilers and stringency of the standard. Since NSPS apply to new, modified, or reconstructed boilers, emission reductions will be greater in each successive year beyond 1990.

I. Refinery Fluid Catalytic Cracking (FCC) Regenerator NSPS

This rule affects new, modified, or reconstructed FCC regenerators at petroleum refineries. An NSPS for particulate and CO emissions from FCCU was promulgated in 1974; and this category, therefore, was not included on the NSPS priority list.

II. Schedule:

Proposal 1/84

Promulgation 4/85

III. Need for Action:

No court-ordered, statutory, or internal EPA deadlines.

IV. Key Issues:

The key issue is the cost effectiveness of the NSPS. The best control system for reducing SO₂ emissions is flue gas desulfurization (FGD). Reduction catalysts, which are not fully developed on FCC units, are less effective in controlling SO₂, but are potentially more cost effective in terms of cost per incremental pollution removed. The proposed NSPS is based on a trade-off between emissions and costs and is designed to allow the use of either FGD or reduction catalysts.

V. Nature of Impacts:

If all new units used FGD, fifth year SO₂ emission reductions would be about 76,000 tons per year. If all new units used regeneration catalysts, the fifth year reductions would be about 70,000 tons per year. Since NSPS apply to new, modified, or reconstructed facilities, emission reductions will be incrementally greater in each successive year, as will the difference between the impact of FGD versus reduction catalysts.

I. Onshore Natural Gas Processing NSPS

The rule affects new, modified, or reconstructed sweetening and sulfur recovery units in the natural gas production industry. This source category is one of the 56 categories on the NSPS priority list.

II. Schedule:

Proposal 1/84

Promulgation 1/86

III. Need for Action:

Section 111 of the Clean Air Act requires that NSPS be promulgated for all source categories on the priority list by August 1982. The project is tracked in ATS and SPMS.

IV. Key Issues:

The key issue is cost effectiveness of SO₂ control. While more stringent emission control systems have been demonstrated commercially the proposed NSPS is based on controls that do not exceed \$1900/ton of SO₂ removed. More stringent controls are economically affordable and could be required by the NSPS if benefits of SO₂ control are perceived to be greater than \$1900/ton.

V. Nature of Impacts:

The proposed NSPS would reduce SO₂ emissions by 95,000 tons/year in the fifth year after implementation. Since NSPS apply to new, modified, and reconstructed facilities, the emission reductions will be incrementally greater than 95,000 tons/year in each successive year.

I. Revision of NSPS for Fossil Fuel Fired Steam Generators, Subpart D (30-day rolling average):

The proposal affects large industrial and utility steam generators (> 250 million BTU/hr) constructed after August 17, 1971. Electric utility units constructed after September 18, 1978, would not be affected by this revision since they are subject to Subpart Da. The revision would establish the averaging time for determining compliance with the NSPS on a 30-day rolling average basis using continuous monitors as the compliance method. The current compliance method is a 3-hour stack test.

II. Schedule:

Proposal	10/83
Promulgation	10/85

III. Need for Action:

The regulation's compliance provisions for units burning complying coal are blank, and this absence of guidance has led to inconsistency among States in interpreting the NSPS. No statutory or court-ordered deadlines exist. The project is tracked in ATS.

IV. Key Issue:

The major issue is the selection of an appropriate averaging time. OAQPS views the revision as a technical correction that fills a void in the regulation and makes the NSPS consistent with the original technical basis (coal sulfur variability was not understood when the NSPS originally was promulgated so no averaging time was specified with the emission limit). NRDC has stated that they will litigate a 30-day rolling average on the basis that it represents an unjustified relaxation of the current NSPS. They maintain that the NSPS is a 3-hour average (a position that OGC believes has strong legal merit), that EPA has been lax in enforcement, and that NSPS should be a 3-hour average standard continuously enforced. The utility industry supports 30-day averaging (the averaging time for today's new boilers under Subpart Da) and would litigate any substantially shorter averaging time as being a retroactive and unjustified tightening of the NSPS.

V. Nature of Impacts:

The potential averaging times range from 3-hours to 30-days. Shorter averaging times will produce lower SO₂ emissions. Approximately 200 coal-fired industrial and utility steam generators are subject to Subpart D. About half comply by burning low sulfur coal and half use flue gas desulfurization (FGD) systems. The proposed 30-day rolling average would have practically no effect on current SO₂ emissions from Subpart D units. Depending on the compliance and enforcement conventions adopted with a 3-hour averaging time, most of these units could be out of compliance. Since there is very little coal in the U.S. reserve base capable of meeting the NSPS emission limit on a 3-hour basis, most of the Subpart D

units that burn low sulfur coal would be forced to retrofit FGD systems. In addition, many of the units now using FGD would require upgrading to comply on a 3-hour basis. Averaging times in the range of 3-hours, therefore, would impose additional capital and operating costs on the electric utilities and interrupt ongoing coal contracts.

I. Review of NSPS for Electric Utility Steam Generators (Subpart Da)

The purpose of the review is to determine if the NSPS for utility steam generators should be revised. The review will assess advances in the state-of-the-art in SO₂, particulate, and NO_x emission control technology. If the review indicates that the NSPS does not reflect best demonstrated control technology (considering energy, environmental, and economic impacts), then a rulemaking will commence.

II. Schedule:

Review 1/86

III. Need for Action:

Section 111 of the Clean Air Act requires that each NSPS be reviewed and, if appropriate, revised every 4 years.

IV. Key Issues:

The major issue will be whether or not to revise the SO₂ standard. Because of major contribution of utilities to SO₂ emissions, concern over acid deposition may generate pressure to tighten the SO₂ standard. Advancements in demonstrated SO₂ control technology appear to be relatively modest. The technical review of Subpart Da probably will serve to prove that the controversially tough position the Agency took on the state-of-the-art of flue gas desulfurization performance was justified. Little further SO₂ reductions from NSPS are likely at this time based on control technology advancement. If, however, the Agency's goal is to reduce SO₂ emissions, then the maximum emission limit in the standard could be revised to preclude the use of high sulfur coals in new sources. A lower emission limit would reduce SO₂ emissions, but would run counter to one of the objectives of the 1977 Clean Air Act Amendments--to foster the use of locally available coal. Lowering the emission limit would generate substantial concern by eastern coal producers and would be difficult to sustain under the current Act.

V. Nature of Impacts:

The impact of a revised SO₂ NSPS would depend on how aggressive the Agency wants to be, but any revision directionally would reduce SO₂ emissions.

I. Revisions to the Guideline on Air Quality Models

The purpose of this action is to amend 40 CFR 51.24 and 40 CFR 52.21 to refer to an updated and revised Guideline on Air Quality Models and to prepare that guideline document.

II. Schedule

Proposal 12/84

Promulgation 3/86

III. Need for Action

The "Guideline on Air Quality Models" is widely used both by EPA in reviewing PSD permits and State Implementation Plan (SIP) revisions and by private industry and States in the preparation of PSD permits and SIP revisions. The guideline serves as a means by which consistency is maintained in air quality analyses. At the time of the initial release of this guidance in 1978, EPA anticipated that periodic revisions would be necessary, since air quality modeling is a rapidly expanding field. Revisions were presented at public meetings in October 1980. Public comments from those meetings indicated that considerable effort was needed to respond appropriately to various technical concerns. As a consequence, programs were begun to solve the technical problems identified during those meetings. Although many of these programs will be continuing for several years, there is sufficient new information now available to revise the guideline and respond to the public concerns identified in 1980. Furthermore, much of the information in the 1978 guide is obsolete and no longer used by Regional Offices. A new guide reflecting current policy and procedures is needed.

IV. Key Issues

There are six main issues associated with this rulemaking: (1) timeliness of the action given the potential impact of CAA revisions; (2) the models selected for inclusion in the guideline and for "preferred status"; (3) demonstration requirements for the user of other models; (4) the need for regulatory consistency vs scientific flexibility; (5) potential conservatism of model estimates; (6) a variety of technical issues including such topics as meteorological data requirements, variations in plume behavior and selection of receptor sites. Each of these issues has been resolved in the guideline development process and accepted through Red Border review.

V. Nature of Impacts

It is anticipated that this action will have minimal impact. The revised guidance is already being implemented under the 1978 guideline or as a result of supplemental guidance contained in "Regional Workshops on Air Quality Modeling: A Summary Report," EPA-450/4-82-015. The revised guideline more clearly organizes this guidance and formalizes it in the regulations.

I. Addressing Uncertainty in Model Estimates

This effort is designed to examine the potential impact on regulatory control strategies of addressing uncertainties in model estimates. Procedures being developed will allow the decision maker to understand the extent to which (1) the ambient standards may be overprotected or (2) the ambient standards may not be protected and to make a reasoned judgment on the appropriateness of emission limits. This program could lead to a policy change regarding the way States express emission limits and/or the way the Agency interprets the attainment provisions of the Act.

II. Schedule

The program is currently separated into two activities (1) accounting for model uncertainty and (2) the effect of emission rate variation. Current program commitments specify that preliminary examples of the potential effect that consideration of uncertainty may have on emission limits be completed early FY 85. Continuation of the effort to account for emission rate variation is anticipated in FY 85 with guidance to Regions and States following.

III. Need for Action

There are no specific statutory nor regulatory requirements for development of the subject guidance. See, however, discussion under IV.

IV. Key Issues

A. EMISSION RATE VARIATION. Sources where the emission rate varies substantially over short periods of time, such as coal-fired power plants, are not adequately addressed by the normal procedures for establishing emission limits. Emission limits based on the maximum emission rate possible may overestimate the potential environmental impact of the source because the maximum rate is achieved only rarely and may not occur under the meteorological conditions most conducive to maximum concentrations. Emission limits based on variable rates of emission requires the development of criteria that allow acceptable risks of violations to be considered.

B. UNCERTAINTY IN MODELING. There are inherent uncertainties in ambient concentrations predicted by air quality dispersion models. They result from two primary causes: (1) inability of the model to precisely represent the random nature of atmospheric dispersion, and (2) imprecision in the measurement of source characteristics or ambient conditions.

V. Nature of Impacts

A. EMISSION RATE VARIATION. The class of sources potentially affected by this program includes coal-fired power plants, nonferrous smelters, and petroleum refineries. While efforts to quantify the impact on power plants is proceeding, the actual impact will depend on the stringency level chosen as the benchmark against which source impacts will be compared.

8. UNCERTAINTY IN MODELING. The actual impact on emission limits and thereby sulfur dioxide loadings is difficult to predict. The primary intent of this effort is to provide the decision maker with a quantitative assessment of the quality of any particular decision. An analysis, not yet underway, could be conducted to examine the impact of specific decision criteria on the establishment of emission limitations and to compare with current operating practice.

I. Title and Short Description - Continuous Emission Monitoring (CEM) Implementation

During FY 1985, SSCD, through its Continuous Compliance Strategy (CCS) guidance and the SPMS, specified that each Regional Office initiate at least a minimum CEM program, with priority attention being given to fossil-fuel-fired steam generators subject to NSPS Subparts D and Da. Additional (non-NSPS), larger SO₂ emitting boilers may be given high priority attention in subsequent years. The Agency believes that continuous monitoring of SO₂ emissions may possibly lead to reductions from such sources.

II. Schedule

This new initiative will start in FY 1985. It may be expanded to address additional (non-NSPS) large boilers in subsequent years.

III. Need for Action

This initiative was undertaken as a result of SSCD's re-examination of the overall compliance status of stationary sources of air pollution and agency compliance techniques and strategies. The results of this examination were reported in two documents entitled: (A) "Compliance Strategy for Stationary Sources of Air Pollution" (dated January 1984); and (B) "Strategy to Assure Continuous Compliance by Stationary Sources of Air Pollution" (dated April 1, 1984).

IV. Key Issues

- A. Are there SO₂ emissions from sources which could be reduced if the Agency increased its CEM efforts? SSCD believes that the answer is in the affirmative. However, the basis for this opinion is not well quantified. Therefore, a number of items, including the following, should be addressed first.
 - emission standards are. This must include not only the numerical values of the standards but also their averaging periods, the numbers and types of exemptions, and the compliance test methods.
 - o Given such an understanding, do the key SO₂ emitters exceed their standards (based upon credible CEM data)?
- B. If excess SO₂ emissions are identified by the CEMs, will the State agencies require the sources to reduce their emissions, or will they simply relax the SIPs (up to the source's emission level)?
- C. Will the Agency apply resources and give priority attention to a SO₂ reduction plan based on expanded implementation of a CEM program?

V. Nature of Impacts

SSCD's FY 1985 CEM initiative, at the most, will result in continuous SO₂ monitoring at about 200 NSPS boilers. There's currently virtually no reliable data upon which to estimate how much excess SO₂ emissions come from these units. However, it is believed that such units are substantially in compliance. Therefore, one would expect very little, if any, SO₂ emission reduction to result from the initiative. Furthermore, if there were any to be obtained, due to technical and programmatic lag-time, they probably would not occur until FY 1986 or later.

To the extent that the CEM initiative is expanded after FY 1985 to address non-NSPS, large SO₂ emitting sources, it is estimated that such a program could yield measurable SO₂ emission reductions. This presumes that the CEM data documents a measurable quantity of excess SO₂ emissions (above that allowed in each SIP) and that the States enforce their SIPs rather than relaxing them. However, the quantitative basis for reasonably estimating the potential reductions from these sources is not available, nor are there any specific plans to acquire such data.

I. Fine Particle NAAQS

This secondary standard would define acceptable ambient levels for fine particles (those smaller than 2.5 μ m) and be based mainly on visibility effects. Because sulfates derived from SO₂ emissions are a major component of fine particle levels, such a standard could materially affect SO₂ SIPs.

II. Schedule

Proposal	9/86
Promulgation	9/87
Compliance	"Reasonable time"

III. Need for Action

In the PM₁₀ proposal, the Administrator deferred a decision on a possible secondary fine particle standard to await further developments relating to acid deposition and analysis conducted by the visibility task force. Two environmental groups have issued an intent to bring suit to force the Agency to make the decision as a part of the current PM standard revision.

IV. Key Issues

The principal basis for consideration of a secondary fine particle standard is related to relatively well quantified effects on visibility. The key issues are:

- 1) Whether a secondary NAAQS for fine particles is needed to protect or improve visibility.
- 2) What minimum level(s) of visibility impairment by fine particles constitute an adverse effect on public welfare.
- 3) Whether the standard should be set to focus only on the eastern portion of the U.S. or include the west.
- 4) How would such a secondary standard be implemented, given the complexities of long range transport multiple source impacts, and substantial costs.

V. Nature of Impacts

The impacts of this action could be minimal to substantial depending on the level of the standard selected and the ultimate implementation requirements imposed by the Agency. The original staff range of interest for a seasonal (3 month average) fine particle standard (8 to 25 μ g/m³) is bounded at the upper end by current conditions and at the lower end by natural background. Quantitative analyses of the

impacts of alternative standards are not available but some idea can be inferred from the draft analysis of alternative regional SO_x strategies conducted by SAI. In this analysis, a 12 million ton SO_2 emission reduction costing approximately \$9 billion/yr would result in visual range improvements on the order of 20 to 30% in large regions of the eastern U.S. The estimated economic benefits of such improvements range from \$1 to 4 billion/year. Implementation of a fine particle standard (as opposed to a sulfate standard) would likely involve control of other sources of particle emissions as well.

ACID RAIN--FLEXIBILITY OF COMPLIANCE

Question: If SO₂ reductions are required, as part of the acid rain controls, has EPA considered flexible compliance options, in lieu of scrubbers or other coal cleaning equipment?

Answer: The Administration is strongly opposed to the implementation of a major acid rain control program at this time. We do not believe that the current state of knowledge can sustain any judgement with respect to the level of emission reductions needed to prevent or eliminate damage. Although we cannot be certain that any particular control program will produce the desired benefits in reducing environmental damage, we are certain that the economic costs would be high. In this situation, it is premature to enact a control program. However, as part of our ongoing analysis of acid rain, we are considering flexible compliance options.

Question: Specifically, has EPA considered expanding the use of the bubble and other trading policies, or the use of natural gas, as ways to reduce compliance costs?

Answer: As part of EPA's ongoing analysis of acid rain policy, we have considered the potential application of bubble and trading policies and possible substitution of natural gas and low sulfur coal for high sulfur fuels. It has been our preliminary view that a carefully designed program would make some provisions for emissions trading since emissions trading can result in less costly emission reductions. Care must be taken, however, in establishing the circumstances in which trading is allowed in order to ensure that emission reduction targets are actually achieved.

ENVIRONMENTAL TOXICITY AND AGING

Question: Last year the Conference Report accompanying the HUD-Independent Agencies Appropriation Bill for FY 1986 included report language that urged EPA to continue improving its environmental analysis related to aging, working with the Quality Assurance Support Laboratory to achieve this objective. How will EPA utilize the expertise of the Quality Assurance Support Laboratory to develop an integrated environmental assessment program on aging?

Answer: The EPA does not have a Quality Assurance Support Laboratory, as referred to in your question, although it does have a Quality Assurance Management staff that develops, implements and audits quality assurance procedures throughout the Agency. The Agency's Health Effects Research Laboratory (HERL) has the lead responsibility for the integrated environmental assessment program on aging.

EPA began its investigations of environmental toxicity and the aging process with a workshop sponsored by the EPA-funded interagency Task Force on Environmental Cancer, Heart and Lung Disease. This activity was referred to in EPA's FY 1986 Appropriations Conference Report. Since then, the Agency has commissioned cooperatively with the National Institute of Environmental Health Sciences (NIEHS) a more comprehensive \$320,000 study of the topic by the National Academy of Sciences. The objectives of this study are:

- o To define current understanding of (a) aging populations and processes, (b) age-related changes in biochemistry that affect the body's ability to detoxify chemicals, (c) the effects of chemicals on the aging process, chronic disease states, and on geriatric health, and (d) potential chemical interactions between drugs and environmental pollutants. The scope of work also calls for development of a broadly defined national research agenda.
- o To recommend specific research issues and needs.
- o To discuss present and future impacts that research on aging has on human health, develop critical hypotheses for research, and establish priorities for a research program.

While we await the findings of this in-depth study (due in the spring of 1987), HERL is preparing a geriatric animal colony which is now leaving middle age. This activity is being conducted in anticipation of future research on toxicity and aging.

STUDY OF ENVIRONMENTAL TOXICITY AND AGING

Question: To what extent does the EPA's present program to study environmental toxicity and aging take into account the following factors: a) the need to integrate the activities of several offices into a single program; b) the need for a multidisciplinary team of environmental and exposure monitoring professionals to plan, execute and evaluate the program (i.e. medical doctors, environmental engineers, pharmacologists, physiologists, etc.); c) the need for sophisticated analytical equipment and laboratory facilities and a staff qualified in their use; d) the need for a cohort of aged individuals in an ongoing experimental program and for whom physiological baseline information and medical histories are already available?

Answer: Because the issues are complex, the Agency has solicited help from the National Academy of Sciences (NAS) on identifying the critical questions. The Agency has deferred making complete decisions on the extent and nature of its research program until the NAS report is finished. The animal colony referred to in the previous answer is being developed for use by all disciplinary units in the Health Effects Research Laboratory (HERL) that may engage in research on toxicity and aging. It is expected that the eventual design of a research program would involve exclusive use of animals from this colony for consistency and integration.

While we await the findings of the NAS report, several studies of an integrated nature using the aging animal colony are contained in the President's Budget for FY 1987. They involve work on reproductive senescence, susceptibility to disease, neurotoxicity, and effects on critical organ systems (pulmonary, cardiovascular, and renal). These studies are integrated across the relevant divisions of HERL. The Agency's research program in this area will continue to be designed to maximize utilization by as many program offices as possible. The timetable for such research will be set after the NAS report is delivered and the program is more firmly established.

The Agency is engaged in several studies on aged humans at its clinical research facility. These include effects of ozone on chronic obstructive pulmonary disease, and the effects of carbon monoxide on ischemic heart disease and behavior. The facility is also joint-funding with the National Institutes of Health, the University of North Carolina, and other institutions a longitudinal study of lung growth, starting with children aged 2 and 1/2, and expecting to follow the aging process throughout development.

